

Exhibit E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. :MASTER FILE NO:
PELVIC REPAIR SYSTEM :2:12-MD-02327
PRODUCTS LIABILITY LITIGATION :MDL NO. 2327
:
:JOSEPH R. GOODWIN
:U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO ALL :
WAVE 4 - TVT & General re :
Prolift :
:
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— — —
MARCH 15, 2017
— — —

Oral sworn deposition of NICOLE B.
FLEISCHMANN, M.D., held at RIKER DANZIG SCHERER
HYLAND & PERRETTI, LLP, Headquarters Plaza, One
Speedwell Avenue, Morristown, New Jersey,
before Margaret M. Reihl, RPR, CCR, CRR, CLR
and Notary Public, on the above date,
commencing at 10:32 a.m., there being present:

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Nicole B. Fleischmann, M.D.

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1 (Documents marked for identification as
2 Nicole Fleischmann Deposition Exhibit Nos. 1
3 through 5, inclusive.)

4 ... NICOLE FLEISCHMANN, M.D., having
5 been duly sworn as a witness, was examined and
6 testified as follows ...

7 BY MR. SLATER:

8 Q. Good morning, Dr. Fleischmann. You know
9 me, I'm Adam Slater, I'm going to take your deposition
10 now.

11 Do I need to give you any instructions?

12 A. If you like to.

13 Q. Sure. You need to just tell the truth,
14 you know that, right?

15 A. Yes.

16 Q. If I ask you a question that doesn't
17 make sense to you for any reason, please let me know,
18 and I'll reask the question, okay?

19 A. Okay.

20 Q. The good thing with no video is I can go
21 as fast as I want. In front of you is a series of
22 documents, do you see this right here? We marked them
23 NF-1 through 5. I just want to go through these
24 exhibits real quick.

1 A. Sure.

2 Q. NF-1 is the deposition notice response
3 from defense counsel.

4 Have you seen that?

5 A. Yes, I have.

6 Q. In response to this deposition notice,
7 did you produce any documents?

8 A. I did not.

9 MR. SLATER: Now, we have a flash drive
10 here, which I guess we'll mark as 6.

11 (Document marked for identification as
12 Nicole Fleischmann Deposition Exhibit No. 6.)

13 MS. KABBASH: I can represent to you on
14 the record that that flash drive that you've
15 marked as Exhibit 6 contains the materials that
16 are set forth on Dr. Fleischmann's supplemental
17 general reliance list.

18 BY MR. SLATER:

19 Q. Dr. Fleischmann, have you produced your
20 invoices for your work in this case?

21 A. No, I haven't.

22 Q. How much have you -- rephrase.

23 I saw in your report and you have your
24 billing rates, so those rates apply, right?

1 A. Yes.

2 Q. Okay. How much time have you spent in
3 connection with the reports on the Prolift®, Prolift+M®
4 and Gynemesh® PS that we're here to depose you on?

5 A. About 100 hours.

6 Q. And, again, I just don't have it in
7 front of me, what's your billing rate for that time?

8 A. 500 per hour.

9 Q. Does that include that time, the time
10 preparing for this deposition?

11 A. No, that does not.

12 Q. How much time did you spend preparing?

13 A. I haven't added it up yet, but I would
14 say it's approximately about 50 hours.

15 Q. What are you billing for the time during
16 the deposition itself for today?

17 A. I bill \$7,500 for the day.

18 Q. So you're billing \$7,500 for this
19 deposition?

20 A. Yes.

21 MR. SLATER: Off the record.

22 (Discussion off the record.)

23 MR. SLATER: I'm not going to ask about
24 the cumulative billing by Dr. Fleischmann

1 because my practice and my understanding from
2 my interactions with defense counsel today and
3 other cases has been that we ask about --
4 obviously, in this case I've asked what time
5 was spent on the reports I'm going to depose
6 Dr. Fleischmann on, but my understanding has
7 always been that both sides respect the fact
8 that we're not going to ask experts what
9 they've billed over all across the litigation,
10 understanding if I asked it you would object
11 anyway, right?

12 MS. KABBASH: For purposes of this
13 deposition, yes, that's correct.

14 MR. SLATER: And, frankly, as liaison
15 counsel for New Jersey, having a lot of
16 involvement in this, that's always been my
17 understanding, and I've enforced that and it's
18 been enforced against me. So to the extent
19 this record will have any use in the future for
20 people, that, to my understanding, is the rule,
21 and it benefits both sides.

22 Okay, moving forward.

23 BY MR. SLATER:

24 Q. Exhibit 2 is a copy of the expert report

1 I was given. Is that the report --

2 A. Yes, it is.

3 Q. -- on Prolift®, Prolift+M® and Gynemesh®

4 PS?

5 A. Yes, it is.

6 Q. Does this contain the opinions that you
7 are offering on these products?

8 A. Yes.

9 Q. Throughout the report you went into
10 quite a bit of detail describing facts, facts from
11 literature, facts from documents, facts from your own
12 background. Did you set forth those facts that were
13 most important to you in forming your opinions when you
14 wrote this report?

15 A. Yes.

16 Q. In the course of the report, you cited
17 specifically some articles, obviously less articles
18 than are listed on your reliance list. Are those the
19 articles that you felt were most important to you in
20 forming your opinions?

21 A. They were among the articles that were
22 most important to me, yes.

23 Q. Is there some other article that you
24 didn't mention in your report that you would say to me

1 this article is very important also to my opinions
2 beyond those you actually discussed in the report?

3 A. I think the main articles that I rely on
4 are in this report.

5 Q. There's no others that you would point
6 to right now?

7 A. Well, I mean, there are some articles
8 that I reviewed in the course of my deposition prep
9 that have come to my attention, but I don't think that
10 my opinions have changed very much from this.

11 Q. This is my question: Are there any
12 articles you could point to right now, other than those
13 listed in the report where you say, you know, if I
14 could redo my report right now, I would make sure I
15 also cited this article also because it's very
16 important to my opinions as well?

17 Is there anything that you could point
18 to?

19 A. It depends on how the deposition goes
20 because there may be things that you ask me that I
21 would rely on other articles for.

22 Q. Not my question.

23 My question is, as you sit here right
24 now before I've asked you anything substantive, having

1 formed your opinions and getting to write your own
2 report in this litigation, are there any articles that
3 you would say I didn't specifically cite to that
4 article or discuss it in my report, but it's one that,
5 as I sit here now, I can tell you is very important to
6 my opinions, and if I were to rewrite my report right
7 now, I would add that article in because it's that
8 important? Is there anything like that?

9 A. Put it this way, there are articles that
10 I did not add to my report that I find are important
11 articles.

12 Q. Okay. Which ones?

13 A. I actually gave you a copy of my notes,
14 and in my notes there are some articles that are not in
15 my report, that are on my notes list.

16 MS. KABBASH: We haven't given him a
17 copy of your notes yet. She has reference
18 notes.

19 THE WITNESS: I have reference notes.
20 You're welcome to have a copy of it.

21 MR. SLATER: Can I see that, so I may
22 refer to it.

23 MS. KABBASH: We made copies of it, if
24 you would like it. So I'd be happy to give it

1 to you.

2 THE WITNESS: I think that would be
3 comprehensive for you.

4 MR. SLATER: Do you have an extra, or
5 you just have the one -- you have it anyway, so
6 I can mark this?

7 THE WITNESS: I have a copy and then we
8 gave you a copy.

9 (Document marked for identification as
10 Nicole Fleischmann Deposition Exhibit No. 7.)

11 MR. SLATER: I marked as Exhibit 7 --

12 MS. KABBASH: Do you want a copy?

13 MR. SLATER: Sure.

14 BY MR. SLATER:

15 Q. I marked as Exhibit 7 a document that
16 says Prolift® notes.

17 What is that?

18 A. These are the notes that I created
19 throughout the hours where I prepared for my
20 deposition, and a lot of these articles are already in
21 my report. They're medical literature.

22 Q. So to the extent medical literature
23 appears within the report or on this Prolift® notes
24 document, those are the articles that to you are most

1 important in forming your opinions?

2 A. Exactly.

3 Q. With regard to internal documents from
4 Ethicon, you mentioned several in your report or
5 documents that were -- let me rephrase it.

6 You mentioned some documents that were
7 created by Ethicon in your report and you discussed
8 them specifically. Were those the Ethicon documents
9 that were most important to you in forming your
10 opinions?

11 A. Can you give me an example, please.

12 Q. You talked about professional education
13 PowerPoint, for example.

14 A. Okay, yes.

15 Q. You talked about the IFUs, you talked
16 about patient brochures, you talked about the surgical
17 technique, you talked about the monograph.

18 A. Yes.

19 Q. Okay. There were various -- we're going
20 to get to it, but there's various documents listed on
21 your reliance materials which are internal documents
22 from Ethicon. If they're not described in your report,
23 were they still of significance to you?

24 A. They are probably documents that I

1 reviewed, but I did not find significant enough to put
2 in my report.

3 Q. Let's go to Exhibit 3. I think that
4 that is your CV. Is that an up-to-date, current CV?

5 A. Yes.

6 Q. Let's go to the next document, which is
7 4, that's your original reliance list of materials
8 relied upon, correct?

9 A. Yes.

10 Q. Exhibit 5 is titled "Supplemental
11 General Reliance List."

12 Is this the reliance list that we should
13 rely on as being comprehensive of what you've reviewed
14 and relied on in this case?

15 A. Yes.

16 Q. If you look at your Supplemental General
17 Reliance List, after the medical literature you get to
18 a section that's titled "Production Materials," and
19 those appear to me to be documents that are Ethicon
20 documents that were produced, and they have Bates
21 numbers attached to most of them, correct?

22 A. Yes.

23 Q. Did you read all these documents?

24 A. I believe I have at least perused these

1 documents, but not in depth.

2 Q. Would peruse mean that you might have
3 shuffled through a pile and seen the cover and gone to
4 the next one?

5 MS. KABBASH: Objection to form.

6 THE WITNESS: Possibly. I think that
7 some of these I recognize on here as documents
8 that I have read, and others I don't recognize
9 as well.

10 BY MR. SLATER:

11 Q. There's a lot of documents on here with
12 reference to the TVT products. Is that because this
13 list is comprehensive of materials you've reviewed in
14 connection with TVT reports as well as Prolift[®],
15 Prolift+M[®] and Gynemesh[®] PS?

16 A. Yes.

17 Q. Are you specifically relying on any of
18 the TVT documents listed on here for your opinions on
19 the Prolift[®], Prolift+M[®] or Gynemesh[®] PS?

20 A. I think when I -- I think the answer to
21 that is yes.

22 Q. In what sense?

23 A. That TVT is a procedure that has been
24 around for 20 years and that the mesh is very similar

1 to Prolift®, and I certainly consider that when I think
2 about my opinions on Prolift®.

3 Q. Go, if you could, to the third page of
4 your production materials.

5 A. The third page of the production
6 materials.

7 Q. Yeah. Don't go back. The heading is
8 "Production Materials."

9 A. Okay, yes.

10 Q. And go to the third page of it, little
11 more than halfway down, and it's a document dated
12 May 3, 2006. It says, e-mail string, top one from
13 David Robinson to Carolyn Brennan regarding Suzette
14 e-mail discussing problems with Prolift®.

15 Do you see that?

16 A. Yes.

17 Q. Do you know what that document is?

18 A. Not offhand.

19 Q. The next document says 2/2/26, notes
20 from meeting with Dr. V. Lucente and Dr. M. Murphy to
21 discuss Prolift® RCT.

22 Do you know what that document is?

23 A. No, not offhand.

24 Q. Dr. Lucente is Dr. Vincent Lucente,

1 correct?

2 A. Yes.

3 Q. Is he the doctor who trained you on the
4 Prolift®?

5 A. Yes.

6 Q. Do you respect Dr. Lucente?

7 A. I don't know him personally. I mean, I
8 don't know as a person, I have no opinion.

9 Q. Okay. When you were trained by
10 Dr. Lucente, did you believe what he told you?

11 A. Yes.

12 Q. Did Dr. Lucente describe the results
13 that you could expect with the Prolift® as he trained
14 you, based on data, studies, that sort of thing?

15 A. No, not that I recall.

16 Q. Are you familiar with the fact that
17 Dr. Lucente has published literature regarding the
18 Prolift®?

19 A. Yes.

20 Q. Is that literature part of what you rely
21 on for your opinions?

22 A. Sure.

23 Q. Is it your assumption that when
24 Dr. Lucente and his group have published data regarding

1 the Prolift® that the data has been accurately
2 presented?

3 A. Yes.

4 Q. If Dr. Lucente's data actually was not
5 accurately presented -- well, let me ask you this
6 question: Has anyone ever suggested to you before
7 right now that Dr. Lucente has not accurately
8 represented the outcomes of his Prolift® surgeries?

9 A. No.

10 Q. Has anyone ever told you that that's
11 been challenged at any time?

12 A. I'm sure it has been.

13 Q. Well, I'm asking you if anyone has ever
14 told you that it's been challenged?

15 A. No, but I'm not shocked to hear that.

16 MR. SLATER: Move to strike from "but"
17 forward.

18 BY MR. SLATER:

19 Q. Has anyone ever told you that anyone
20 within Ethicon was of the view that Dr. Lucente and his
21 group published data that was not accurate?

22 MS. KABBASH: Objection to form.

23 You can answer.

24 THE WITNESS: It may be in these

1 e-mails, but I had not personally been told
2 that.

3 BY MR. SLATER:

4 Q. And if it's in these e-mails, you did
5 not read the e-mails that are listed here that said
6 that?

7 A. Not that I recall.

8 Q. So, as you sit here right now, you're
9 not aware of anybody within Ethicon expressing the view
10 that Dr. Lucente and his group have published data
11 that's not accurate with regard to his Prolift®
12 outcomes?

13 A. Right.

14 Q. Has anybody ever told you that
15 Dr. Lucente's data, which was evaluated through an IIS
16 grant from Ethicon, was reviewed by an outside expert,
17 meaning not Lucente and not Ethicon?

18 Did you know that that was done?

19 A. No.

20 Q. Would you accept that Dr. Lucente is
21 knowledgeable regarding the Prolift® and the risks and
22 complications that can arise from a Prolift®?

23 A. I accept that he is, yes.

24 Q. Do you know what Ethicon internally

1 believes are the known complications and risks with
2 regard to the Prolift®?

3 A. I don't believe that Ethicon has any
4 other understanding of what the known risks are than
5 the risks that are in -- that are known to all of us.

6 Q. And those would be the risks that are
7 listed in the IFU, for example?

8 A. Among the IFU and in the clinical
9 literature.

10 Q. Okay. In terms of -- I want to just get
11 vocabulary together.

12 When I talk about the Prolift® -- let me
13 ask you this: With regard to the Prolift® and
14 Prolift+M®, is there any difference, from your
15 perspective, in terms of the risk-benefit profile?

16 A. No.

17 Q. Meaning the same benefits are sought to
18 be achieved and the same risks would exist with both
19 products?

20 A. Yes.

21 Q. Does the same hold true for Gynemesh®
22 PS?

23 A. Yes.

24 Q. One source of information that you

1 obtained when you were first trained on the Prolift®
2 was information from Ethicon regarding their
3 understanding of the benefits and risks, correct?

4 A. It was one source, yes.

5 Q. To the extent Ethicon provided
6 information, you as an expert, I'm asking you now, were
7 they obligated to provide the truth about what they
8 knew?

9 A. One would hope that they were providing
10 the truth, yes.

11 Q. Well, as an expert witness, if Ethicon
12 did not provide truthful information about the risks
13 that they knew existed with the Prolift®, you would
14 criticize that, correct?

15 A. I would if it was the only information
16 that I had at that time.

17 Q. All right. So you're saying if you --
18 rephrase.

19 So you're saying that there's
20 circumstances in which it would be okay for Ethicon to
21 not disclose risks that they know?

22 MS. KABBASH: Objection to form.

23 THE WITNESS: If there were clinical
24 risks that were known, I would expect that the

1 company would have told me about them.

2 BY MR. SLATER:

3 Q. If there were clinical risks known to
4 Ethicon regarding the Prolift®, the Prolift+M® or
5 Gynemesh® PS, they should have disclosed those,
6 correct?

7 A. If they knew them, yes.

8 Q. Do you know what risks were known to
9 Ethicon as of the date the Prolift® first went on the
10 market? Have you ever seen anything indicating a list
11 of risks they knew existed?

12 A. I've read some internal documents on
13 that, yes.

14 Q. What internal documents are you
15 referring to?

16 A. I've looked over some depositions, Owens
17 deposition.

18 MS. KABBASH: That may not be on the
19 list Adam. That was recently provided to
20 Dr. Fleischmann, the Charlotte Owens
21 deposition. Very recently she was sent the
22 Charlotte Owens deposition on Prolift®.

23 BY MR. SLATER:

24 Q. Anything else?

1 A. Just reviewing the literature that
2 Ethicon knew based on the TVM data that was available
3 at that time.

4 Q. Have you ever seen an analysis of the
5 TVM data that was prepared by somebody other than an
6 Ethicon employee or one of the investigators?

7 A. An analysis of the TVM data besides one
8 of the investigators?

9 Q. Or by Ethicon itself.

10 A. No, I'm not sure.

11 Q. Are you aware of whether there's been
12 anybody who's had access to the TVM raw data and done
13 their own analysis of the outcomes?

14 A. No.

15 Q. Are you aware of something called the
16 study of Gynemesh® PS, clinical study of that; do you
17 know that there was a study conducted?

18 A. No, but I'm happy to look at it.

19 Q. You haven't seen it before today, right?

20 A. I'm not sure.

21 Q. You're not aware of it?

22 A. Not offhand.

23 Q. In the materials list there is a list of
24 company witness depositions, still in Exhibit 5, the

1 supplemental reliance list, there's a company witness
2 depositions list.

3 Do you see that?

4 A. Yes. Am I on the right page?

5 Q. No, you're not.

6 A. Oh, I'm sorry.

7 Q. The list of company witness depositions,
8 is that complete if you were to add Charlotte Owens?

9 A. Yes.

10 Q. Do you know what dates transcripts of
11 Charlotte Owens you saw?

12 A. I believe they're from 2012.

13 Q. Was it a one day, two days?

14 A. It was a two-day deposition, 2012. I'm
15 not entirely sure.

16 Q. You saw both days?

17 A. Yes.

18 Q. Was that important to you?

19 A. It enlightened me about some of the
20 things that were going on with the company at that
21 time, but it was not important to my opinions about
22 Prolift®.

23 Q. With regard to the depositions that are
24 listed on this page, the materials list, company

1 witness depositions, Piet Hinoul, two days of
2 depositions, was that of significance to you?

3 A. I can't say that I went into that one
4 in-depth.

5 Q. You can remember reading it?

6 A. I did read it at one point, but not
7 recently.

8 Q. Is there anything in that you can tell
9 me now was of any significance to you?

10 A. Not offhand.

11 Q. Charles Nager, was that of any
12 significance?

13 A. Same.

14 Q. Marty Weisberg, there's four different
15 days listed, any significance to that?

16 A. Same, I don't recall specifically what's
17 in those depositions.

18 Q. Since it's not listed here, you were
19 never given Axel Arnaud's depositions, were you?

20 A. I don't think so, no.

21 Q. Did you want to be provided whatever
22 depositions may have been taken that would provide
23 information as to what Ethicon knew about the risks and
24 benefits of the Prolift®?

1 A. Again, these were not of primary
2 importance to me when I was forming my opinions about
3 Prolift®.

4 Q. I don't want to put words in your mouth,
5 although I do, let me ask you this: With regard to
6 your opinions on the risks and benefits of the
7 Prolift®, did you consider at all what Ethicon knew as
8 to the risks and benefits, or did you form your opinion
9 based on what you've read in the literature and your
10 own experience?

11 A. At the time or now?

12 Q. As you sit here right now, we'll wind
13 backwards, but as you sit here right now, what is your
14 opinion based upon?

15 A. My opinion is mostly based upon the
16 clinical literature and my own experience.

17 Q. When you first were training on the
18 Prolift® and first starting to use it in terms of your
19 understanding of the risks and benefits, was that based
20 in part on what Ethicon informed you about the risks
21 and benefits?

22 A. It was not.

23 Q. Well, you were trained by Ethicon,
24 right? It's a simple question; you were trained by

1 Ethicon, right?

2 A. On Prolift®, yes.

3 Q. Okay. You saw the IFU, right?

4 A. At some point, yes.

5 Q. You read the IFU, right?

6 A. I believe so, yes.

7 Q. You believed it to be a true statement,
8 right?

9 A. Yes.

10 Q. Okay. To the extent Ethicon identified
11 adverse reactions or risks or any other information,
12 that was part of what your understanding was, correct?

13 A. Yes.

14 Q. You assumed that Ethicon, which is a
15 large pharmaceutical company employing professionals
16 and consulting with doctors, including the TVM group,
17 in that they would have used that, those sources of
18 information to give you the best information they had
19 about what are the risks and benefits, correct?

20 A. Yes, but there was a lot of other
21 information that I had at that time that was probably
22 more important to me than what I was reading in the IFU
23 or what a rep was telling me.

24 MR. SLATER: Move to strike from "but"

1 forward.

2 BY MR. SLATER:

3 Q. If Ethicon disclosed to you a
4 significant risk, a risk that could cause very serious
5 harm to a patient associated with the Prolift®, you
6 would have incorporated that into your understanding,
7 correct?

8 A. Yes.

9 Q. When you consented patients, you would
10 tell the patients your understanding of the risks and
11 benefits, correct?

12 A. Yes.

13 Q. And that's because the patient has to
14 decide whether to have this procedure and this device
15 put in their body; it's their decision, right?

16 A. Correct.

17 Q. And you as a physician would want to
18 make sure that you gave them the risk-benefit profile
19 so they would understand here's the benefits you could
20 get, but these are the risks, including the most severe
21 things that can happen just so you, the patient, can
22 decide what's best for you, right?

23 A. Correct.

24 Q. So the extent, again, that Ethicon would

1 tell you about severe risks, you would tell that to
2 your patients so the patient could consider that,
3 correct?

4 A. Yes, luckily that was not the only
5 information I was relying upon at the time.

6 MR. SLATER: Move to strike after "yes".

7 BY MR. SLATER:

8 Q. Do you know what sources of information
9 Ethicon had and has had regarding the complications
10 caused by the Prolift®, the Prolift+M® and Gynemesh®
11 PS? Do you know how Ethicon gets that information?

12 A. I know that they look at the MAUDE
13 database, and there are reports to them directly.

14 Q. Anything else?

15 A. The clinical literature.

16 Q. Anything else?

17 A. Anecdotes.

18 Q. What's an anecdote?

19 A. A physician e-mail.

20 Q. Any other sources?

21 A. They rely on the medical community to
22 tell them about their complications.

23 Q. And that's the medical community around
24 the world, correct?

1 A. Yes.

2 Q. To the extent Ethicon knows about severe
3 complications that can have a permanent impact on a
4 woman from all those various sources, they should
5 consider that with regard to whether the design is
6 safe, correct? They should take it into account,
7 right?

8 A. Yes.

9 Q. And they should make sure they warn
10 physicians who are considering using the product and
11 who are going to have to consent patients, they should
12 give that information to the doctors so they can give
13 that information to patients so the patient can make an
14 informed decision on whether or not to consent,
15 correct?

16 MS. KABBASH: Objection to form.

17 THE WITNESS: I just -- I have trouble
18 with the way you're phrasing these questions
19 because physicians don't only rely on what they
20 hear from the company to make a decision about
21 what the risks and benefits of a procedure are.

22 MR. SLATER: Move to strike.

23 BY MR. SLATER:

24 Q. My question is what Ethicon is supposed

1 to do. I'm not talking about -- but let me ask the
2 question again differently. Maybe I'll do a better
3 job, it's unlikely, but I'll try.

4 To the extent Ethicon knows about severe
5 complications that can occur with the Prolift®, the
6 Prolift+M®, the Gynemesh PS®, they needed to make sure
7 that they gave that information to physicians so
8 physicians could incorporate that into their knowledge
9 base and make sure that they could tell patients not
10 only the benefits that could be achieved but also here
11 are the risks, including the most severe things that
12 can happen, so the patient could make an informed
13 decision, correct?

14 MS. KABBASH: Objection to form.

15 THE WITNESS: Yes, and you asked me that
16 question already, and I said yes.

17 MR. SLATER: Thank you. Move to strike
18 after "yes".

19 BY MR. SLATER:

20 Q. You don't have to laugh at me. I'm
21 doing the best I can.

22 A. Me too.

23 Q. If you go further in your materials
24 list, it goes to other materials and you have publicly

1 available materials, including a bunch of practice
2 bulletins and other information issued by professional
3 organizations, right?

4 A. Okay.

5 Q. That's part of what you considered?

6 A. Yes.

7 Q. Have you ever taken any of the committee
8 opinions or practice bulletins or physician statements,
9 these various statements from these organizations like
10 AUGS, SUFU and all of these organizations and actually
11 read them and then consulted the references that were
12 cited to go see if the references were accurately cited
13 for what they were cited for?

14 Have you ever done that type of
15 cross-checking?

16 A. Yes, I have.

17 Q. With which ones, any ones in particular?

18 A. With many of them.

19 Q. Have you ever noticed any
20 inconsistencies between the proposition something was
21 cited for and what the source document actually said?

22 A. No, I didn't.

23 Q. So if you're on the witness stand in
24 front of a jury and we show you one that shows a

1 discrepancy, that would be just something you didn't
2 notice when you did the review?

3 A. Well, you'd have to give me a specific.

4 Q. If you go further you get to expert
5 reports, there's three expert reports listed?

6 A. Where are we? Oh, here, I got it.

7 Q. Are those of any significance to you in
8 forming your opinions in connection with the Prolift[®],
9 Prolift+M[®] or Gynemesh[®] PS, Blaivas, Kohli and
10 Rosenzweig?

11 A. Not really.

12 Q. Okay. Turning to the next page, there's
13 a series of depositions in the MDL wave cases.

14 Were those of significance to you?

15 A. Not particularly.

16 Q. Did you read any of them?

17 A. Are we talking about the MDL wave cases
18 in general?

19 Q. The depositions listed.

20 A. With regards to Prolift[®] because there's
21 a lot of depositions here.

22 Q. Let's start with all of them. Did you
23 read any of these depositions?

24 A. Yes, I did.

1 Q. Which ones did you actually read?

2 A. I read ones that were pertinent to
3 Prolift®, a couple of them.

4 Q. Which ones?

5 A. Alan Garely's. I read Dan Elliott's.
6 We're talking specifically about Prolift®?

7 Q. We're talking about this whole list
8 right here. I want to know what you read on this list,
9 not limited to Prolift®.

10 A. Well, I've read these depositions but
11 not recently. The most recent ones that I have read
12 have been the ones with regard to Prolift®.

13 Q. There's no deposition regarding Prolift®
14 for Dan Elliott listed here, is there?

15 A. Yes, there is.

16 Q. Am I overlooking it?

17 A. Oh, I'm looking under expert reports. I
18 apologize.

19 Q. Let's start over. In the list of
20 depositions on this page under the heading "MDL Wave
21 Cases" --

22 A. Yes.

23 Q. -- did you read any of these
24 depositions?

1 A. I have, but the only one I've read
2 recently is Alan Garely's on Prolift®.

3 Q. You know Dr. Garely, right?

4 A. Not personally.

5 Q. You know who he is?

6 A. I know who he is, but I don't know him
7 personally.

8 Q. Did you read any of the other
9 depositions on this list of depositions?

10 A. Yes, but not recently.

11 Q. Anything in those that are of any
12 significance to you, as you sit here right now?

13 A. Not offhand.

14 Q. There's a list of expert reports further
15 down on this page. Did you read those expert reports
16 or any of them?

17 A. Yes, I've read the ones recently that
18 have had to do with Prolift®.

19 Q. Which ones?

20 A. Alan Garely's and the Elliott Prolift®.

21 Q. Did you ever see Dr. Elliott's
22 deposition or any deposition of him regarding the
23 Prolift®?

24 A. I believe I have. Yes, I believe I

1 have, although I don't see it on the reliance list.

2 Q. Is there anything of any significance to
3 that now that you can tell me?

4 A. Not really.

5 Q. Going to the last page, there's more
6 expert reports.

7 Did you read any of those on the last
8 page of this list?

9 A. At some point, but not recently.

10 Q. Anything of any significance on this
11 page, this last page of expert reports?

12 A. Not particularly.

13 Q. Let's look at your Prolift® notes,
14 Exhibit 7.

15 "Early TVM studies," that's one of your
16 headings, right?

17 A. Yes.

18 Q. Those are important articles for you in
19 forming your opinions, right?

20 A. They were articles I wanted to be aware
21 of when I was preparing for my deposition.

22 Q. These are articles written by the
23 doctors who actually invented and developed the
24 Prolift®, correct?

1 A. Yes.

2 Q. Would you consider this literature to be
3 important?

4 A. Sure.

5 Q. You write here "Berrocal" and you write
6 "concept." What does that mean, "concept"?

7 A. I'm just referring to the paper that he
8 wrote which discussed the concept of Prolift®.

9 Q. Is that what your takeaway was from that
10 article, that it talks about the concept?

11 A. Yes.

12 Q. Was there anything else about that
13 article that was significant to you?

14 A. I don't recall.

15 Q. I didn't see any discussion of anything
16 in the article that went beyond really that, but I want
17 to know because this is my time to depose you, is there
18 anything else about the Berrocal article which was
19 published in 2004, right?

20 A. Yes.

21 Q. Anything else about that that's
22 significant to you?

23 A. Not offhand, but if you show me the
24 article, we can discuss any particular specifics in

1 there.

2 Q. You don't remember what it says?

3 A. I remembered that it talked about the
4 concept of Prolift®.

5 Q. Do you remember anything else about the
6 article?

7 A. Not particularly.

8 Q. You prepared for about 50 hours for this
9 deposition?

10 A. Yes.

11 Q. Did you review that article as part of
12 your preparation?

13 A. Yes, I did.

14 Q. And still the only takeaway you have is
15 that it talked about the concept?

16 A. Yes, and the details of the concept of
17 Prolift®.

18 Q. Did they talk about any troubling
19 complications or risks with the procedure?

20 A. Not in that article.

21 Q. Are you sure about that?

22 A. No, not sure, but I don't recall that it
23 did talk about that.

24 Q. Nothing that you cited in your report,

1 right?

2 A. Right.

3 Q. To the extent they talked about
4 complications of concern, that would be something that
5 you would have wanted to note in your analysis, right?

6 A. Yes, but there were other articles that
7 discussed that.

8 MR. SLATER: Move to strike from "but"
9 forward.

10 BY MR. SLATER:

11 Q. Do you recall, and maybe this will
12 refresh your recollection, they talked about their
13 concern over retraction of mesh in the human body?

14 A. In the TVM article, yes.

15 Q. In the Berrocal article?

16 A. Well, if you'd show it to me, I'm happy
17 to look at it.

18 Q. I don't have it.

19 A. Yeah, I don't have it either.

20 Q. I have it here.

21 A. Good.

22 Q. It is good. You don't know, do you?

23 A. I don't have a photocopy.

24 Q. I pointed to my head, by the way.

1 A. I don't have a photographed copy of it
2 in my brain like you do.

3 Q. You don't even remember that it
4 discussed retraction, do you?

5 A. It may have. I will defer to you on
6 that.

7 Q. You don't remember, as you sit here now,
8 whether that article discussed retraction or not,
9 right?

10 A. No, but I will take that it did, if you
11 say it did.

12 Q. I'm not trying to -- my question is
13 this: You don't recall whether that article even
14 discussed retraction, do you?

15 A. No, I don't recall.

16 Q. Do you know whether the French TVM group
17 were concerned about retraction/contraction of the mesh
18 throughout the time the Prolift® was being developed
19 and marketed? Do you know whether they were concerned?

20 A. Yes, I believe they were.

21 Q. These were doctors who probably had as
22 much, if not more experience with the Prolift® than any
23 doctors in the world, right?

24 A. At that point, yes.

1 Q. Well, you're not saying you had more
2 experience at any time in your life with the Prolift®
3 than they did, are you?

4 A. I wasn't referring to myself. I was
5 just saying at that time they were the ones that had
6 the most experience.

7 Q. Is there some doctor you could point to
8 who at any point had more experience with the Prolift®
9 than the French TVM group?

10 A. Currently, I believe there are a lot of
11 doctors that used Prolift® for a very long time, maybe
12 not as long as they did, but a very long time.

13 Q. And who are those that you would think
14 had more experience with the Prolift® than TVM group?

15 MS. KABBASH: Objection to form.

16 THE WITNESS: I can't give you names,
17 but I can tell you that there are people who
18 have been doing Prolift® for a long time, since
19 it was first invented.

20 MR. SLATER: Move to strike.

21 BY MR. SLATER:

22 Q. I'm asking for names. Can you name
23 anybody, any doctor in the world that had more
24 experience with the Prolift® than the French TVM group?

1 A. I mean, I can tell you Lucente had a
2 very longstanding experience with TVM, and he was not
3 in the French group. Miller.

4 Q. Miller. Miller had a lot of experience
5 with the Prolift®?

6 A. Dan Miller, wasn't he on there? Yes.

7 Q. Dennis Miller.

8 A. Dennis Miller, I'm sorry.

9 Q. That's okay.
10 Anybody else?

11 A. No, but I'm sure I could come up with
12 people who were doing Prolift® for a long time.

13 Q. Well, my question was this, not who do
14 you know of that did a lot of Prolift® surgeries, my
15 question is this: Is there any doctor in the world you
16 can point to that had more experience with the Prolift®
17 than the French TVM group?

18 A. Not more.

19 Q. Is there any doctor in the world you
20 could point to who had as much experience with the
21 Prolift® as the French TVM group?

22 A. I just gave you two names.

23 Q. Lucente and Dennis Miller, those are the
24 two?

1 A. Yes.

2 Q. You've never seen Lucente's internal
3 data, right?

4 A. No.

5 Q. His actual raw internal data,
6 spreadsheets from his patients, nothing like that?

7 A. No, no, I have not, no.

8 Q. Do you know whether the French TVM group
9 thought that the Prolift® should be used in only a
10 limited spectrum of patients? Obviously, patients with
11 prolapse, but do you know whether they thought that it
12 should be limited in who it's used in at any point in
13 time?

14 A. I know they thought it was ideal in
15 patients who had higher grades of prolapse.

16 Q. A higher grade of prolapse would be a
17 clear stage 3 or a 4?

18 A. Yes.

19 Q. When did you learn -- well, rephrase.
20 From the time -- rephrase.

21 At the time you first started using the
22 Prolift®, what was your patient selection criteria?

23 A. The same.

24 Q. Got a clear stage 3 or a 4?

1 A. Well, I was always taught in my training
2 that stage 1 and 2 prolapse really didn't need surgery.

3 Q. Do you know whether there were any
4 other -- rephrase.

5 Do you know of any other limitations
6 that the TVM group thought should be placed on the use
7 of Prolift®?

8 A. No. Oh, with the exception of pregnant
9 patients.

10 Q. So you thought the only limitations on
11 the use of Prolift® should be high grade prolapse,
12 stage 3 and 4 and pregnant women?

13 A. I don't think that they said that there
14 was a limitation on stage 3 and 4 prolapse. I just
15 think they said it was ideal for that case.

16 Q. Would you agree with me that a physician
17 could follow the proper procedure for implanting a
18 Prolift® and erosion can occur?

19 A. Yes.

20 Q. And I use the word erosion to include
21 erosion, exposure, extrusion when I ask that question.

22 Is the answer the same?

23 A. Erosion, extrusion.

24 Q. Yeah. The question is this: Do you

1 agree that a doctor can follow the correct procedure,
2 implant the Prolift® properly and an exposure or an
3 erosion or an extrusion can still occur?

4 A. Do you mean an erosion into an organ?

5 Q. Either way.

6 A. No. An extrusion, yes.

7 Q. You think that an erosion into an organ
8 can only happen if the doctor doesn't put in the
9 Prolift® correctly?

10 A. If the dissection is not correct,
11 exactly.

12 Q. What about the dissection would lead the
13 Prolift® to erode into the bladder?

14 A. Probably an unrecognized bladder injury
15 at the time of surgery or just being way too close to
16 the urethral area of the bladder.

17 Q. Do you agree or disagree that the
18 Prolift® can through the inflammatory reaction and its
19 reaction with the adjoining tissue erode into the
20 bladder, even if it's placed in the right place in the
21 right way?

22 You disagree with that?

23 A. I do disagree with that.

24 Q. Do you know what Ethicon thinks about

1 that?

2 A. No.

3 Q. If they think that can happen, do you
4 disagree with Ethicon?

5 A. Yes.

6 MS. KABBASH: Objection to form.

7 THE WITNESS: I do.

8 BY MR. SLATER:

9 Q. Do you know whether the TVM group, any
10 of their members ever published that there should be
11 caution taken in determining who should actually get a
12 Prolift® put in their body?

13 MS. KABBASH: Objection to form.

14 BY MR. SLATER:

15 Q. They actually used that word in that
16 published article.

17 Did you ever see that?

18 A. No, I don't recall that, that wording.

19 Q. Did you ever see an article that had
20 words to the effect -- rephrase.

21 Did you ever see an article which Cosson
22 was one of the authors where part of the takeaway was
23 that the use of Gynemesh® Prolene soft mesh as part of
24 this procedure turned out to have too many risks and

1 that they may have to find a completely different
2 material because of the problems they were seeing.

3 Did you ever see that article?

4 MS. KABBASH: Objection to form, lack of
5 foundation.

6 THE WITNESS: No, I have not seen an
7 article on that, a peer-reviewed article on
8 that.

9 BY MR. SLATER:

10 Q. You never saw that, okay.

11 What are you using currently to treat --
12 rephrase.

13 If a patient comes in now to your
14 practice, I'm not talking about this second, but in
15 this time frame, here in 2017, with a cystocele, for
16 example, one option is to do a suture repair, a
17 colporrhaphy, correct?

18 A. Yes.

19 Q. That's something you do in your
20 practice, right?

21 A. Occasionally.

22 Q. What are the other procedures that you
23 do besides colporrhaphy to treat a cystocele?

24 A. I'll do a colporrhaphy, I'll augment it

1 with a graft, usually a biologic graft, if I'm going to
2 do that, although that's not very common. I will do a
3 sacrocolpopexy.

4 Q. You do a sacrocolpopexy to treat a
5 cystocele?

6 A. If there's uterine prolapse.

7 Q. Let's say there's not. Let's just say
8 it's a cystocele, AS, you can cross off the list,
9 right?

10 A. No.

11 Q. You do abdominal sacrocolpopexy just to
12 treat cystoceles?

13 A. Yes.

14 Q. Really, okay, what else?

15 A. In an older patient I'll do a
16 colpocleisis.

17 Q. Are you currently using any
18 polypropylene synthetic mesh through the vagina to
19 treat cystoceles?

20 A. No.

21 Q. Are you currently using any
22 polypropylene mesh through the vagina to treat
23 rectoceles?

24 A. No.

1 Q. Are you currently using any
2 polypropylene mesh through the vagina to treat any type
3 of prolapse?

4 A. Not in a while.

5 Q. When is the last time you used mesh,
6 polypropylene mesh through the vagina to treat any type
7 of prolapse?

8 A. About 2013.

9 Q. Is that due to your risk-benefit
10 analysis?

11 A. No. That's due to the fact that a
12 product that I was very happy with was pulled from the
13 market, and there was not really another one that I
14 found to be equal.

15 Q. The product that was pulled off the
16 market was the Prolift® and the Prolift+M®?

17 A. Yes.

18 Q. Why don't you use Gynemesh® PS cut by
19 you to fit the defect through the vagina?

20 A. I used to do that.

21 Q. I'm asking why you don't do it now?

22 A. Because when I was doing the Sonin(ph.)
23 approach with Gynemesh® PS, I was getting more pelvic
24 pain than I liked, so I stopped doing that when

1 Prolift® came out.

2 Q. Do you use Gynemesh® PS in your
3 practice?

4 A. No, not really.

5 Q. You do abdominal sacrocolpopexy,
6 correct?

7 A. Yes.

8 Q. What mesh do you use?

9 A. A Y mesh, I was using the Bard for a
10 while, and now I'm using Coloplast Restorelle mesh.

11 Q. When you say "Y mesh," you're talking
12 about the shape of the mesh or a specific brand?

13 A. No, there's many brands of Y mesh. It's
14 just a specific company.

15 Q. So since -- well, rephrase.

16 You said you stopped putting mesh in
17 through the vagina around 2013. The Prolift® and
18 Prolift+M® were pulled off the market in 2012.

19 Was that the last time you put mesh in
20 through the vagina to treat prolapse?

21 MS. KABBASH: Objection to form.

22 THE WITNESS: No.

23 BY MR. SLATER:

24 Q. After the Prolift® and Prolift+M® were

1 withdrawn from the market, what, if any, mesh did you
2 place through the vagina to treat prolapse from the
3 time that they were withdrawn from the market to that
4 time in 2013 when you ceased?

5 A. I briefly trialed the Coloplast product,
6 which was the only at that point trocar product,
7 trocar-based product that resembled Prolift® to me, but
8 I was not happy with it, so I stopped doing it. And
9 now that's no longer available.

10 Q. It's a good thing.

11 MR. SLATER: Off the record.

12 (Discussion off the record.)

13 BY MR. SLATER:

14 Q. Do you accept that there are some women
15 who as a result of the Prolift® have suffered what can
16 fairly be described as catastrophic permanent
17 complications?

18 Do you agree with that?

19 A. As a result of the Prolift®?

20 Q. Yes.

21 A. As a result of the product?

22 Q. As a result of the Prolift® being put in
23 their body and being in their body, yes.

24 A. It's not as a result of the Prolift®.

1 It's a result of how the Prolift® was placed.

2 Q. You're saying that you think that can
3 only happen when the doctor doesn't do the procedure
4 correctly?

5 A. A catastrophic?

6 Q. Yeah.

7 A. Absolutely.

8 Q. Are you aware that there are some
9 physicians, including those that you would consider to
10 be the most highly skilled physicians in the world with
11 the Prolift® to have had that type of outcome?

12 MS. KABBASH: Objection to form and lack
13 of foundation.

14 THE WITNESS: If that's the case, it's
15 extremely rare.

16 BY MR. SLATER:

17 Q. You don't know though, do you?

18 MS. KABBASH: Objection.

19 THE WITNESS: Yes, I do.

20 BY MR. SLATER:

21 Q. You know that that has happened, or you
22 know that --

23 A. I know that it would be extremely rare
24 for a catastrophic event to happen with someone who is

1 very well trained at putting in a Prolift®.

2 Q. You just said it would be. Do you know
3 that that has actually occurred though? I'm not
4 talking hypothetically here. Do you know that that's
5 actually occurred?

6 A. There may be an occurrence, but I'm not
7 saying that that is a common thing.

8 Q. You're saying there may be -- are you
9 acknowledging that it has happened, or are you saying
10 you're not sure if it's happened, but you'll accept
11 that it probably has? Which one is it?

12 MS. KABBASH: Objection.

13 THE WITNESS: I'm saying that I'll
14 accept that it probably has.

15 BY MR. SLATER:

16 Q. Do you know what Ethicon's view is as to
17 whether or not the Prolift® can be put in properly and
18 a woman can still suffer a catastrophic, permanent
19 complication from the Prolift® itself?

20 A. I know that Ethicon asked that its
21 surgeons to be well trained in putting -- in pelvic
22 surgery, in all pelvic surgery before embarking on
23 using a Prolift®.

24 Q. Let's talk about your experience with

1 the Prolift®. You were trained by Ethicon, correct, by
2 Dr. Lucente at an Ethicon event, correct?

3 A. I really don't consider that my training
4 on Prolift®.

5 Q. Let me ask it differently. You attended
6 an Ethicon professional education training session that
7 was run by Dr. Lucente, correct?

8 A. I did.

9 Q. You learned things during that seminar,
10 correct?

11 A. Yes.

12 Q. Okay. You took that into account in
13 moving forward with patients, correct? That was part
14 of what you took into account?

15 A. Yes.

16 Q. I believe there came a point in time
17 when you modified your procedure for implanting a
18 Prolift®; is that correct?

19 A. Yes.

20 Q. When did that occur?

21 A. Pretty early on in my using it.

22 Q. Can you tell me when?

23 A. When, I didn't hear you say, when or
24 why?

1 Q. Can you tell me when?

2 A. When I started modifying Prolift® was
3 probably almost immediately when I adapted it.

4 Q. Would that be within 2007 then?

5 A. Yes. Trying to get my time frame.

6 Q. Can you tell me specifically the
7 modification you made to your procedure?

8 A. I was trying to recreate what I had
9 learned when I was putting in the Gynemesh® PS before I
10 started using Prolift®, which was to access the
11 sacrospinous ligament from an anterior approach,
12 meaning that we would go through an incision on the
13 anterior vaginal wall to get to the sacrospinous
14 ligament. That's how I learned to place the Gynemesh®
15 PS because it gave me a deep repair of the apex of the
16 vagina, and you have to remember that I was operating
17 on people with advanced prolapse, and it is my opinion
18 that anybody who has a large cystocele has apical
19 prolapse, not just my opinion, but many people's
20 opinion.

21 So I was trying to recreate that in a
22 way that the anterior only did not allow me to do.

23 Q. That's what you were doing initially?

24 A. Yes.

1 Q. What was the change to your procedure,
2 or did I misunderstand? I thought there was a point in
3 time when you modified your Prolift® procedure?

4 A. I did.

5 Q. What was the modification?

6 A. So exactly that, I would take the
7 Prolift® but I would cut the back straps of the
8 posterior part repair -- I would almost have to draw it
9 for you because it's hard to explain.

10 Q. You don't need to draw it. I'm pretty
11 familiar.

12 A. So I would cut the back straps off the
13 Prolift®, the P side and I would sew it with Prolene to
14 the A side, so that I would have a shape that had six
15 legs coming from it, and the deep legs I would put
16 through the sacrospinous ligament from an anterior
17 approach.

18 Q. Who taught you to do that?

19 A. It was a modification that closely
20 resembled what I had been doing in my fellowship. So
21 in my fellowship, we would take capios and we would put
22 the Gynemesh® into the sacral spinous ligament from the
23 same approach.

24 Q. It was Vince Lucente who suggested this

1 modification to you, correct?

2 A. He may have suggested it, but it was
3 something that I had been thinking about, how I could
4 do that same kind of repair that I had been doing in my
5 fellowship with the Prolift®.

6 Q. If you wrote in a document, for a while
7 I considered going back to my previous repair until I
8 was clued into the modified total repair by Lucente in
9 an informal meeting, would that be an accurate
10 statement that it was Dr. Lucente?

11 A. It might have been that. It could have
12 been.

13 Q. So just to get this clean, Dr. Lucente
14 suggested this modification to the procedure, correct?

15 A. Yes, I guess he did.

16 Q. Okay. And did you feel that that
17 modification improved your outcomes?

18 A. It improved my outcomes, yes, but not as
19 much as I wanted.

20 Q. My understanding is that when the
21 Prolift+M® came out, you began to use the Prolift+M®,
22 correct?

23 A. Yes.

24 Q. And my understanding is that, from your

1 perspective, your outcomes improved when you started
2 using the Prolift+M[®], correct?

3 A. No. It wasn't because of the M. It was
4 because I had at that point, and even before I started
5 using the M, I had gone back to doing a total -- to
6 total repair, and that's when my outcomes started to
7 really improve.

8 Q. If you wrote in a document that with the
9 advent of M, the outcomes are getting better and
10 better, you would stand by that statement if you wrote
11 that, wouldn't you?

12 MS. KABBASH: Objection to form.

13 THE WITNESS: It depends on when I wrote
14 the document.

15 BY MR. SLATER:

16 Q. November of 2009?

17 A. Right. So I had done Prolift[®] after
18 that for another three years, and my feeling is my
19 outcomes had gotten better because of the way that I
20 was doing the Prolift[®] after I modified the approach --
21 after I went back to the total approach is when my
22 outcomes started getting really better.

23 Q. The modification to your procedure, is
24 that something that Ethicon placed into the IFU as an

1 alternative way to place the Prolift®?

2 A. No.

3 Q. So your outcomes would not be
4 representative of other physicians not using the same
5 procedure potentially, correct? You had your own
6 modified procedure, right?

7 MS. KABBASH: Objection.

8 THE WITNESS: I did, but I just want to
9 clarify that I went back to the procedure that
10 was done -- that was recommended in the IFU not
11 long after I wrote that letter. It just
12 wouldn't be reflected in that letter, because
13 even when I modified the approach, I was still
14 not getting some apical prolapse.

15 MR. SLATER: Move to strike from "but"
16 forward.

17 BY MR. SLATER:

18 Q. So my understanding is initially you
19 followed the IFU?

20 A. So initially I really didn't follow the
21 IFU, initially. Very early on, I modified the Prolift®
22 to recreate what I had done in my fellowship.

23 Q. Okay.

24 A. It wasn't until after that letter was

1 written that I actually went back to the IFU approach.

2 Q. Let me walk through this. Initially
3 when you first started doing the Prolift® when you were
4 first trained, you were following this -- a modified
5 procedure similar to what you had been doing with
6 Gynemesh® PS where you did an anterior incision to
7 attach the mesh to the sacrospinous ligament.

8 You described that earlier in the
9 deposition, correct?

10 A. Yes. Can I -- I don't mean to interrupt
11 you. I just want to really clarify this. When I first
12 started Prolift®, my first Prolifts® were A only, just
13 as the IFU, A only, okay. So there was no deep
14 support. So someone would come in with a cystocele and
15 I would just do anterior kit, and I was getting
16 recurrences at the top of the vagina.

17 So when I thought about it, I said to
18 myself this is not exactly what I was doing in my
19 fellowship because I was getting something into the
20 ligament during my fellowship. So that is why I
21 modified the technique probably after speaking to him
22 and seeing how can I get that deeper repair that I'm
23 looking for.

24 So maybe a few months or a few --

1 whatever it was after I started doing Prolift®, I
2 modified the technique, and that's about the time that
3 you see that letter being written.

4 Q. Well, let me understand, your
5 professional education with the Prolift® took place in
6 2007, correct?

7 A. I don't remember if it was 2006 or 2007.

8 Q. Your report says 2007, and I think the
9 documentation in the report was 2007. You actually
10 discuss it when you were trained. It says it right
11 here -- oh, I see what it says, a Prolift®
12 preceptorship and proctorship in 2006 and 2007
13 respectively, okay.

14 So you started using the Prolift® 2006,
15 2007?

16 A. Around there.

17 Q. Okay. Initially, were you following the
18 IFU and then you saw some apical prolapse recurrences?

19 A. Yes.

20 Q. So then you modified your procedure?

21 A. Yes.

22 Q. To get more support from the
23 sacrospinous ligament?

24 A. Yes.

1 Q. Okay. And then at some point you had
2 this conversation with Dr. Lucente where he suggested
3 this modification?

4 A. Yes.

5 Q. When did that occur?

6 A. It probably occurred a few months after
7 I had started doing the Prolift®, at a meeting, or I
8 had seen him somewhere and I came up to him and I said,
9 listen, I'm getting a lot of apical recurrences with
10 the anterior repair, and I said, but I don't want to
11 put mesh on the back wall of the vagina, so how do I do
12 this so that I can still fix my cystoceles and get a
13 deeper repair, and then he said, well, you could try
14 modifying it.

15 Q. And for how long did you use that what
16 I'm going to call the Lucente modification?

17 A. I think that would be bad to do that.

18 MS. KABBASH: Objection to form.

19 BY MR. SLATER:

20 Q. I'm going to call it that for the rest
21 of my life, so let's go.

22 A. Of course. Probably a couple of years.

23 Q. Did there come a point when you stopped
24 following this modification?

1 A. Yes.

2 Q. At that point did you go back to doing
3 the IFU procedure?

4 A. And the difference was then I was
5 starting to do totals, so I started to do the anterior
6 and posterior.

7 Q. If you had just a cystocele with a
8 patient, you wouldn't put a total Prolift® in for just
9 a cystocele, would you?

10 A. You have to remember the philosophy.

11 Q. It's a simple question. No, I don't
12 want to know the philosophy.

13 A. Yes, I would. Yes, I would.

14 Q. So you would put in a total Prolift® in
15 somebody who has no rectal prolapse?

16 A. Who has no rectocele?

17 Q. Right.

18 A. Yes, because, because, recurrences
19 happen in the posterior wall, the posterior apical
20 wall.

21 Q. Right.

22 A. So what I was doing was I was supporting
23 the posterior apical wall behind the uterus with the
24 posterior passes, and then my results became much

1 better.

2 Q. Your results in terms of whether you got
3 recurrences?

4 A. Yes.

5 Q. Okay. But you put all that mesh in just
6 to prevent a recurrence in a compartment that didn't
7 have any prolapse when you operated on the patient,
8 correct?

9 A. Exactly. It's similar to what we do
10 with our Y meshes and colpopexies. We do support the
11 back of the uterus and the back wall of the vagina,
12 even if the patient doesn't have a significant
13 rectocele. That's why Y meshes are not used in
14 colpopexies. It's the same principle.

15 MR. SLATER: Move to strike from
16 "exactly."

17 BY MR. SLATER:

18 Q. The reason that you can get a recurrence
19 in the unoperated compartment that didn't have prolapse
20 initially is because there's a displacement of force
21 once you put the Prolift®, for example, in the anterior
22 portion of the vagina, that is going to displace forces
23 on to the posterior part, so the reason you'd put in
24 mesh in the back, even though there's no prolapse, is

1 because when the force is displaced, now it's going to
2 put more force on the posterior part of the vagina,
3 correct?

4 MS. KABBASH: Objection to form.

5 THE WITNESS: The forces that happen in
6 the pelvis will go to the weakest area of the
7 vagina, which is now the unmeshed area.

8 BY MR. SLATER:

9 Q. Are you aware that there are many
10 physicians that never felt that there was adequate data
11 to support the benefit of putting mesh in the posterior
12 compartment?

13 A. Yes, but I'm also aware of physicians
14 that have found that there are good benefits to mesh in
15 the posterior compartment.

16 MR. SLATER: Move to strike from "but"
17 forward.

18 Let's mark this NF -- I don't have an
19 extra copy of it though.

20 MS. KABBASH: I have it.

21 MR. SLATER: This?

22 MS. KABBASH: Yeah.

23 (Document marked for identification as
24 Nicole Fleischmann Deposition Exhibit No. 8.)

1 BY MR. SLATER:

2 Q. So we've marked as Exhibit 8 this letter
3 you wrote to Scott Jones, November 6, 2009, right?

4 A. Yes.

5 Q. And you described yourself in the first
6 paragraph as "one of your most loyal Prolift® users,"
7 right?

8 A. Yes.

9 Q. You go through some history -- rephrase.
10 The second paragraph you talk about how
11 by the time you finished your fellowship, you had a
12 strong relationship with the company, that's Ethicon,
13 right?

14 A. Yes.

15 Q. And you naturally gravitated to using
16 these products, which you listed above, the TVT and the
17 TVT-O. And then you say, hence the importance of
18 targeting young fellows.

19 That's what you said, right?

20 A. I did.

21 Q. Meaning if you can get the young fellows
22 to become loyal to your products, then they will
23 probably use your products going forward, right?

24 MS. KABBASH: I just want to state a

1 standing objection to questioning on this
2 particular subject matter because you asked her
3 about the same exact language at the Corbett
4 TVT deposition.

5 MR. SLATER: I didn't depose her on the
6 Prolift® that day.

7 MS. KABBASH: I know, and I'm not going
8 to object to questioning related to the
9 Prolift®, but you happened to address that same
10 exact language at the prior deposition, so I'm
11 just going to ask you to move on to other
12 things that are more relevant to Prolift®. I
13 know there's a lot of things in this letter
14 related to Prolift®.

15 MR. SLATER: I'll struggle to do so.

16 BY MR. SLATER:

17 Q. Can you answer that one question?

18 A. I guess I'll answer it the way I
19 answered it when we discussed this back then, which was
20 that this was coming off the heels of a marketing
21 meeting, and so I had that marketing frame of mind when
22 I was talking to them in this letter.

23 Q. When we go down to the fifth paragraph,
24 you talk about your training. In there you say 2005.

1 In your report you said you were trained in 2006, 2007.

2 Can you tell me more specifically? We
3 probably have it somewhere.

4 A. Yeah, I think I would have to sort of
5 ask someone to pull that, if you have that, because I
6 can't remember exactly what year it was, but it was
7 around that time.

8 Q. And you say that your training with
9 Dr. Lucente that day changed your practice forever
10 because he taught you about a full thickness
11 dissection, right?

12 A. Yes.

13 Q. And you say that you got your erosion
14 rate to go down after that, correct?

15 A. Yes.

16 Q. In the last paragraph on the first page
17 you say, I began to do Prolift® anterior for stage 3
18 cystocele and Prolift® total for complete procidentia,
19 correct?

20 A. Exactly.

21 Q. Would you also -- rephrase.

22 When you say you did Prolift® anterior
23 for stage 3, that would also include stage 3 or 4,
24 correct?

1 A. Yes, but stage 4 was more likely to be a
2 complete procidentia, so then I would probably do a
3 total.

4 Q. Okay. Let's go to the second page. At
5 the top you talked about the fact that you started to
6 have apical recurrences, correct?

7 A. Yes.

8 Q. This is what we've been talking about a
9 little bit earlier today.

10 And then you in the next paragraph talk
11 about having an informal meeting with Dr. Lucente, and
12 he clued you into the modified total repair, correct?

13 A. Yes.

14 Q. And that's where you would take the arms
15 from the posterior Prolift®, cut them off and then sew
16 them on to the anterior Prolift® and use that to get
17 additional support for a cystocele and to get
18 additional apical support to prevent an apical
19 recurrence, correct?

20 A. Yes.

21 Q. Where would the arms go, these arms that
22 you sewed on to the anterior Prolift®, where would they
23 go to?

24 A. They would go onto the bottom of the

1 mesh, not close -- close to where the side arms are but
2 just downward.

3 Q. And where would they extend back to,
4 where would they go in the body? Rephrase.

5 So you would sew them on to the body
6 where you just described. Where would you put the mesh
7 after you attached it, where in the body would it be
8 left?

9 A. The same place as if you were doing a
10 total, through the sacrospinous ligament.

11 Q. Okay.

12 A. So I was making the same passes as I
13 would if we were doing a total.

14 Q. If you did that would you note that in
15 your operative report that you had done so?

16 A. Yes.

17 Q. So you would actually say, even for a
18 cystocele repair, we took the posterior, we cut off the
19 arms, we attached them. So if I read one of your
20 operative reports, I would know you did that modified
21 total, correct?

22 A. Yes, it would say that it was configured
23 in the shape of a six legged insect. That's exactly
24 how I would dictate it.

1 MS. KABBASH: Really?

2 THE WITNESS: Yes.

3 BY MR. SLATER:

4 Q. Did you tell your patients that the mesh
5 was going to be configured like a six legged insect in
6 their body?

7 A. No. That was not something I felt the
8 patient needed to understand.

9 Q. Looking at the second paragraph on the
10 second page of this letter you wrote, at the end of the
11 paragraph, you say with the advent of M, that's
12 referring to the Prolift+M®, right?

13 A. Yes.

14 Q. The outcomes are getting better and
15 better. That's what you stated, right?

16 A. Yes, that's what I stated.

17 Q. You were trying to tell the truth to
18 Scott Jones about your experience with Ethicon's
19 products at the time, right?

20 A. Yes.

21 Q. In the third paragraph here on the
22 second page of this letter, you talked about being
23 approached by other manufacturers to try their
24 products, right?

1 A. Yes.

2 Q. And you talk about the AMS Elevate,
3 right?

4 A. Yes.

5 Q. And you talk about an issue with it that
6 you felt made it less optimal than the Prolift®, right?

7 A. Right.

8 Q. And then you say also "the mesh is not
9 my beloved M," right?

10 A. Yes.

11 Q. Again, you were trying to tell Scott
12 Jones truthfully how you felt about the Prolift+M®
13 mesh, correct?

14 A. Yes.

15 Q. Let's look at the last paragraph.

16 In the second sentence you say, "the
17 product needs some advancement: it's only perfect when
18 the surgeon modifies it and you will eventually lose
19 avid users who don't adopt this technique to 'deeper'
20 products."

21 That's what you wrote, right?

22 A. That's what I wrote.

23 Q. To your knowledge, did Ethicon ever
24 promulgate this modified technique that you're talking

1 about?

2 A. No, they did not.

3 Q. You say, "Remember not many pelvic
4 surgeons like putting mesh over the rectum when the
5 main problem is cystocele," correct?

6 A. That's what I said, yes.

7 Q. And that's a true statement, that
8 doctors -- the majority of pelvic surgeons are hesitant
9 to use mesh in the posterior compartment, even if there
10 is a rectocele, correct?

11 A. Yes.

12 MS. KABBASH: Objection to form.

13 THE WITNESS: I was too at the time.

14 BY MR. SLATER:

15 Q. And even up until the time when the
16 Prolift® and Prolift+M® no longer were available, the
17 majority of surgeons, even those who were very familiar
18 with the Prolift® or the Prolift+M®, were very hesitant
19 to put that mesh in the posterior compartment, correct?

20 A. Well, I'm not sure about what the
21 majority of surgeons are, but I felt that way at the
22 time. I don't feel that way now.

23 Q. You said, "Not many pelvic surgeons like
24 putting mesh over the rectum when the main problem is

1 cystocele. It just doesn't make sense."

2 That's what you said, right?

3 A. That's what I felt at the time, yes, but
4 I definitely changed that thinking later on.

5 MR. SLATER: Move to strike from "but"
6 forward.

7 Can we just go off. Take a break for
8 five minutes.

9 MS. KABBASH: Sure.

10 (Brief recess taken at 11:44 a.m.)

11 (Deposition resumes at 11:56 a.m.)

12 BY MR. SLATER:

13 Q. In your report and on your Prolift®
14 notes, you cite to an article from Dietz from 2011
15 regarding ultrasounds.

16 A. Okay.

17 Q. And you rely on that article to say that
18 contraction doesn't occur basically, right?

19 MS. KABBASH: Objection to form.

20 THE WITNESS: Well, that's one of the
21 things that I rely on to say contraction
22 doesn't occur.

23 BY MR. SLATER:

24 Q. The Dietz study from 2011 that was with

1 the Perigee?

2 A. Yes.

3 Q. Not with the Prolift[®], right?

4 A. It is Perigee.

5 Q. It's not with the Prolift[®], Prolift+M[®]
6 or Gynemesh[®] PS, right?

7 A. No, but it's with another polypropylene
8 mesh.

9 MR. SLATER: Move to strike from "but"
10 forward.

11 BY MR. SLATER:

12 Q. All polypropylene meshes are not the
13 same, right?

14 A. No, there's different types of
15 polypropylene meshes.

16 Q. They have varying configurations,
17 varying methods of implant, right?

18 A. Yes.

19 Q. The fiber diameters can vary, right?

20 A. Yes.

21 Q. The pore sizes can vary, right?

22 A. Yes.

23 Q. The elasticity can vary, right?

24 A. Yes.

1 Q. You cited in your list of materials that
2 you reviewed Velemir. It's actually on your list of
3 articles.

4 MS. KABBASH: You mean her reliance
5 list?

6 MR. SLATER: Your reliance list, yeah.

7 THE WITNESS: Not in my notes.

8 BY MR. SLATER:

9 Q. Not in your notes. Velemir, Amblard,
10 "Transvaginal mesh repair of anterior and posterior
11 vaginal wall prolapse: a clinical and ultrasonographic
12 study" published in Ultrasound Obstetrics and
13 Gynecology in 2010.

14 That's on your list, right?

15 A. Yes.

16 Q. Did you read that article?

17 A. At some point I'm sure I did.

18 Q. Do you know what it says?

19 A. It probably talks about retraction.

20 Q. You don't remember anything that article
21 actually says, do you?

22 A. I sort of remember, but not exactly. I
23 remember that they did find some retraction.

24 Q. Some retraction; is that your

1 recollection?

2 A. Yes.

3 Q. Do you remember what percentage of
4 patients in that study, which was actually done with
5 Prolifts®, had retraction that was qualified as
6 moderate or severe?

7 A. I don't remember the number.

8 Q. Do you have any sense of what the
9 percentage was?

10 A. I want to say about 30%.

11 Q. Okay. It was actually closer to about
12 89%. Does that refresh your memory, or you just don't
13 know?

14 MS. KABBASH: I'm just going to request
15 that if you question the witness on the
16 specifics of an article that you present her
17 with a copy of the article.

18 MR. SLATER: I don't have it. I have it
19 here, pointing to my ear.

20 MS. KABBASH: That's fine, but I'm just
21 going to make that ongoing request going
22 forward.

23 MR. SLATER: I got you.

24 BY MR. SLATER:

1 Q. You don't know, though, do you?

2 A. Well, if you say that there was an 89%
3 retraction, I would just want to see the article again
4 to look at what they were doing.

5 Q. Let's talk about Velemir for a couple
6 minutes. Do you know who placed those Prolifts®?

7 A. Probably someone in the original TVM
8 group.

9 Q. You didn't mention that article anywhere
10 in your report at all, did you?

11 A. In my actual report?

12 Q. In your actual report where you told us
13 all the important facts and all your opinions, that
14 article doesn't get mentioned once, does it?

15 A. I don't think so, no.

16 Q. Do you know if somebody from Ethicon
17 medical affairs assisted with that article as well? Do
18 you know whether that was part of the process?

19 A. No, I don't know that.

20 Q. You don't know that Pete Hinoul was
21 acknowledged for his help with that? You don't know
22 that, do you?

23 MS. KABBASH: Same objection.

24 THE WITNESS: If you say so, I'll take

1 it. I don't have the article in front of me.

2 BY MR. SLATER:

3 Q. In forming your opinions, you did not
4 factor in the Velemir article, did you?

5 MS. KABBASH: Objection to form.

6 THE WITNESS: It's on my reference list,
7 so I did read it, but there must be a reason
8 why I didn't put it in there in my report.

9 BY MR. SLATER:

10 Q. Tell me the reason right now.

11 MS. KABBASH: Same objection.

12 THE WITNESS: If you show me the
13 article, I'd be happy to look at it and tell
14 you why. I can't recall enough about the
15 article to tell you why it wasn't in there.

16 BY MR. SLATER:

17 Q. You obviously made a decision that you
18 weren't going to reference the article in your report,
19 right?

20 MS. KABBASH: Objection.

21 MR. SLATER: I'm sorry. What's the
22 objection?

23 MS. KABBASH: Lack of foundation.

24 BY MR. SLATER:

1 Q. Rephrase.

2 You're telling us that you read the
3 Velemir article?

4 A. It's on my reference list.

5 Q. Just because it's on the reference
6 list -- rephrase.

7 Just because it's on the reference list
8 does not mean you read it, correct?

9 A. It means I perused it at some point.
10 I'm sure I did.

11 Q. There was nothing about it that you
12 thought was important enough, obviously, because you
13 didn't mention it in your report, if you did actually
14 read it, right?

15 A. I can't recall the exact findings of the
16 article, what the details of the article was, so I
17 probably made a decision, but I can't recall what it
18 was. If you showed me the article, I would be happy to
19 look at it and tell you why I didn't find that I wanted
20 to put it in my report.

21 Q. So in your report you rely on the Dietz
22 article, that's the one you actually cite to for
23 ultrasound findings with a different product, the
24 Perigee.

1 That's what you actually utilize in your
2 report, right?

3 A. Yes, I put that one in my report.

4 Q. And you didn't actually cite to or you
5 didn't discuss in any way the Velemir article, which
6 was done by doctors in the TVM group who actually
7 placed the mesh and had findings regarding Prolift®
8 retraction that was found on ultrasound? You didn't
9 mention that anywhere in your report, right?

10 MS. KABBASH: Objection.

11 BY MR. SLATER:

12 Q. It's a correct statement, correct? It's
13 not mentioned anywhere in your report, right?

14 A. It's not mentioned in my report, but I
15 will tell you what the TVM group found about retraction
16 was that it was not symptomatic in most cases.

17 MR. SLATER: Move to strike from "but"
18 forward.

19 BY MR. SLATER:

20 Q. That's actually what you think, isn't
21 it, based on the materials you actually reviewed that
22 the TVM group doesn't think that retraction is
23 symptomatic?

24 A. In most cases.

1 Q. Did you see any presentation by
2 Professor Jacquetin in which he talked about Prolift®
3 patients where they were placed at his hospital with a
4 19.6% rate of symptomatic retraction on vaginal
5 examination? Did you ever see that?

6 A. His patients had -- he said that his
7 patients had a 19.6% symptomatic retraction rate?

8 Q. Have you ever seen that presentation?

9 A. No.

10 Q. It's not mentioned anywhere in your
11 report or reliance list, so you have never seen that,
12 right?

13 A. No.

14 Q. And it wasn't something you factored
15 into your opinions, correct, couldn't have factored in
16 if you have never seen it, right?

17 A. No. But it wouldn't negate all the
18 other articles.

19 Q. No, no, Doctor, I have limited time --

20 A. -- that I have seen that have not shown
21 that kind of retraction rate.

22 MS. KABBASH: Adam, I'm going to ask you
23 to let her complete her response, please.

24 MR. SLATER: Move to strike. Move to

1 strike after the "no."

2 BY MR. SLATER:

3 Q. You didn't factor that in because you've
4 never seen it, right?

5 MS. KABBASH: Objection to form.

6 THE WITNESS: I will factor it in, but
7 it will not be the only thing that I consider
8 about retraction.

9 MR. SLATER: Move to strike.

10 BY MR. SLATER:

11 Q. Up until just now when I told you about
12 it, you didn't know that that presentation existed,
13 right?

14 A. If it was not on my reliance list, then
15 I did not review that presentation.

16 Q. Since you didn't know it existed until a
17 few minutes ago, you certainly did not take it into
18 account in forming your opinions that are set forth in
19 your report, correct?

20 A. No, I did not.

21 Q. Are you aware of whether there's any
22 cases that are currently in discovery or going into
23 discovery in which you were involved in the treatment
24 of the patients?

1 MS. KABBASH: You mean in New Jersey?

2 MR. SLATER: Anywhere.

3 THE WITNESS: Any product, any case?

4 BY MR. SLATER:

5 Q. Any case against Ethicon.

6 A. Yes.

7 Q. And what are you aware of?

8 A. I get a notice from Ethicon with the
9 names of patients who have filed some kind of claim.

10 Q. Do you do anything with that
11 information?

12 A. So if the patient is an active patient
13 of mine, then I have to notify them that I'm an expert
14 witness for Ethicon, and I have to send them a letter
15 regarding that.

16 Q. Are you aware of whether any of your
17 cases have not just been filed but the case is actually
18 going into or is in active discovery where you were
19 involved in the treatment of the patient?

20 A. I'm trying to understand the difference.

21 Q. There is a difference between the case
22 just being filed and then where the case actually
23 starts to go through discovery, where the treating
24 doctors have their depositions taken, the plaintiffs

1 get deposited, and the case may actually go on to trial.

2 A. Yes.

3 Q. Are you aware of any of your cases being
4 in that active discovery phase now?

5 A. Yes.

6 Q. What cases?

7 A. I know there is a case in the MDL that
8 is coming up that I was an implant on.

9 Q. Any other cases you're aware of?

10 A. No.

11 Q. When you say it's coming up, what do you
12 mean by that?

13 A. It's coming up in the next crop of MDL
14 cases.

15 Q. How do you know that?

16 A. Because the company has made me aware.

17 Q. How do they make you aware?

18 A. They tell me, usually in writing.

19 Q. Do you have that letter you got about
20 that case?

21 A. I have letters, but I don't have that
22 letter with me.

23 Q. Your report on Page 3 talks about pelvic
24 organ prolapse. You can look at it, if you want.

1 A. Okay. I have my own copy.

2 Q. That's fine, either one.

3 Page 3 and it says, pelvic organ
4 prolapse, when defined by symptoms, has a prevalence of
5 3 to 6% and up to 50% when based upon vaginal
6 examination, right?

7 A. Yes.

8 Q. When you refer to the 50%, that's an
9 anatomic finding?

10 A. Yes.

11 Q. It may be that it is no symptoms; the
12 patient is not even aware of it in some cases, right?

13 A. Or they have other symptoms that are
14 not -- not specifically bulge symptoms, but they are
15 symptoms that we know are related to the prolapse like
16 urinary retention or recurrent urinary tract
17 infections.

18 Q. You state very clearly that prolapse,
19 when defined by symptoms, has a prevalence of 3 to 6%,
20 right?

21 A. Yes, pelvic organ prolapse symptoms,
22 right, bulge symptoms.

23 Q. You don't say the word bulge, right?
24 The word bulge isn't there, right?

1 A. No, it's not there.

2 Q. Of those 3 to 6% of women that have
3 symptoms of prolapse, a very small percentage will
4 actually ever be surgical candidates, correct?

5 A. About 11%.

6 Q. And the 11% you're relying on what,
7 Olson?

8 A. Yes.

9 Q. Nobody can come up with a more recent
10 article, huh?

11 MS. KABBASH: Objection. That wasn't a
12 question. You don't have to answer.

13 BY MR. SLATER:

14 Q. Look at Page 7. You talk about
15 basically an algorithm for how a patient gets worked up
16 in order to determine how a patient should be treated,
17 right? That's kind of what you're talking about there?

18 A. Yeah.

19 Q. And one of the things you say after
20 going through in that first full paragraph, you ask
21 about what her personal life is like, especially with
22 regard to sexual activity, as all this information can
23 be helpful with diagnosing and formulating a treatment
24 plan, right?

1 A. Exactly.

2 Q. And basically for each woman you have to
3 take into account who are you, what's your lifestyle,
4 how old are you, what do you do, as you say here, are
5 you sexually active, do you want to be sexually active,
6 do you plan to be sexually active. All those types of
7 things you have to put into the evaluation so that that
8 woman can be counseled based on her situation, right?

9 A. Correct.

10 Q. And the reason you said especially with
11 regard to sexual activity is because certain treatments
12 pose more risk than others to sexual function, right?

13 A. That's not the only reason.

14 Q. It's one of the reasons, right?

15 A. Well, it goes into our informed consent
16 process, and then it also for me is a decision about
17 whether if a woman is older and not sexually active
18 whether I may want to do a vaginal closure procedure.

19 Q. If a woman is sexually active or wants
20 to be sexually active, you want to take that into
21 account because there are varied risks depending on the
22 treatment that's provided, correct?

23 A. Yes.

24 Q. One of the risks with the Prolift® is

1 that the mesh itself can lead to dyspareunia, correct?

2 A. I don't know. I think the mesh can lead
3 to erosions.

4 Q. Do you agree, not agree or not have an
5 opinion that contraction of Prolift® mesh around the
6 vagina and hardening of the mesh commensurate with that
7 can lead to dyspareunia?

8 A. I think when meshes are placed too
9 tightly, they can lead to dyspareunia.

10 Q. Do you think the only time a Prolift®
11 leads to dyspareunia is when someone places them too
12 tightly?

13 A. When there's too much tension on the
14 mesh, yes, I do believe that.

15 Q. Can you define for me too much tension
16 objectively? What's the objective test for too much
17 tension?

18 MS. KABBASH: Objection to form.

19 THE WITNESS: Are you talking about
20 intraoperatively too much tension?

21 BY MR. SLATER:

22 Q. I'm talking about placing a Prolift®
23 with too much tension, what's the objective test for
24 that?

1 A. Well, in the operating room we're
2 looking to make sure that the mesh is not too tight
3 under the vaginal wall, so we do certain maneuvers or
4 we did when I was doing Prolift® to make sure that the
5 mesh was covering side wall to side wall but wasn't in
6 a band across, because if you put too much tension on
7 the arms, you could feel that. So after we closed the
8 vagina, we would do a maneuver to push up on the mesh
9 and we'd watch the mesh retract inward to the trocars,
10 and then we knew that the tension was not too much.

11 Q. Do you agree that the mesh can be placed
12 without too much tension, meaning the arms aren't
13 pulled taut when the closure occurs, so it's left
14 without what you would consider to be excessive
15 tension, but then due to bridging fibrosis, scar
16 plating and contraction, the meshes can band?

17 A. I think when the mesh is placed flatly
18 under the bladder and not under too much tension,
19 that's an extremely rare event that I would not see in
20 any degree of frequency.

21 Q. Do you agree or disagree that there are
22 very highly skilled, very experienced doctors who did
23 the Prolift® and Prolift+M® who -- let me rephrase it.

24 Do you agree or disagree that there were

1 very highly skilled physicians who placed Prolifts®
2 exactly the right way and ended up with tension banding
3 of the arms despite that?

4 A. I believe there are very highly skilled
5 doctors that may not have placed Prolift® the right way
6 and got that as an outcome.

7 Q. Okay. Did that happen to you?

8 A. Yes.

9 Q. Did you breach the standard of care when
10 you did that?

11 A. I think that it's in our complication
12 informed consent that it's a possibility because we are
13 allowed not to be perfect in medicine, but so we give
14 ourselves a little leeway for that to happen, but I
15 still believe that when you do a perfectly placed
16 Prolift®, that that kind of thing is not going to
17 happen.

18 Q. It's certainly foreseeable that a doctor
19 is not going to place a Prolift® in a, quote, perfectly
20 placed way, right?

21 A. I mean, any procedure is like that.
22 It's not just Prolift®. We are fallible as surgeons,
23 that's why we have risk assessments and complication
24 rates, even the best of us.

1 Q. Did Ethicon -- well, rephrase.

2 And you agree that where a Prolift® is,
3 quote, unquote, not perfectly placed, you can end up
4 with scarring of the mesh that leads to contraction
5 that leads to dyspareunia, correct?

6 A. I believe that when it's not placed
7 well, that that can happen, yes.

8 Q. Has Ethicon ever objectively stated what
9 the right level of tension is, where they've actually
10 given an objective test that a doctor can say, okay,
11 this is not excessively tensioned, I'm following this
12 standard?

13 MS. KABBASH: Objection to form.

14 THE WITNESS: I was trained how to do
15 Prolift®. I was trained on that tensioning
16 technique, and that was the extent of what
17 Ethicon had taught me.

18 BY MR. SLATER:

19 Q. Okay. Did Ethicon teach you when you
20 were trained what would happen to the mesh when pulled
21 on in terms of what would happen to the pores; did
22 Ethicon tell you that?

23 A. No, but I could imagine that if you pull
24 tightly on a mesh the pore size will decrease.

1 Q. You can imagine that now right?

2 MS. KABBASH: Objection.

3 THE WITNESS: I could imagine that the
4 whole time.

5 BY MR. SLATER:

6 Q. You could, but here's the question: Did
7 you? Did you actually cognitively say to yourself,
8 when I pull on the mesh, the pore sizes are going to
9 change, or is that something you'd become aware of just
10 in recent years?

11 A. I can't tell you when I first thought of
12 that or learned that.

13 Q. Ethicon never told you that, right?

14 A. I don't specifically recall Ethicon
15 telling me that, no.

16 Q. Ethicon never warned you about the risks
17 of scar plating and bridging fibrosis leading to
18 clinically symptomatic contraction, did they?

19 A. The whole concept of contraction and
20 scar plating and bridging fibrosis, whatever you want
21 to call it, you know, was something that I had been
22 made aware of very early on in this -- when using this
23 technique. I mean, those kinds of terms had come up
24 very early on, at meetings, but it was always the

1 understanding that it had to do with how the mesh was
2 placed, whether it was folded or bunched because we
3 weren't taking care to place it flatly or we were
4 putting too much tension under it.

5 Q. So your understanding was that if you
6 put it in properly and the mesh wasn't folded or
7 bunched, those things wouldn't happen?

8 A. Not symptomatically, no.

9 Q. On Page 9 at the bottom you're talking
10 about -- you just talked about Baden-Walker, and you
11 just talked about POP-Q, right?

12 A. Right.

13 Q. You say the very bottom of Page 9,
14 "regardless of which measurement system is used, the
15 physician needs to quantify the degree of prolapse and
16 the compartments affected in order to form a treatment
17 plan for the patient," and that's because depending on
18 the nature of the prolapse, you may or may not feel
19 that a Prolift® or Gynemesh® PS or Prolift+M® would be
20 indicated, right?

21 A. Or if surgery is indicated at all.

22 Q. So the reason that you have this
23 language at the bottom of Page 9 is because you need to
24 evaluate the degree of prolapse and the compartments

1 affected to determine, A, is surgery indicated and, B,
2 what type of surgery of the various options, right?

3 A. Right.

4 Q. Were you ever made aware of any
5 increased risks for a patient if both a Prolift® and a
6 TVT-O were placed in the same patient?

7 A. Made aware?

8 Q. Yeah.

9 A. No.

10 Q. Ethicon never notified you of any such
11 increased risk, did they?

12 MS. KABBASH: Objection to form.

13 THE WITNESS: No. We were just told
14 that if -- when doing -- I mean, from the
15 surgeon's monograph and from my training that
16 if you did a mesh repair, you should use a
17 separate incision for the sling.

18 BY MR. SLATER:

19 Q. One of the documents that you reference
20 in your report is the physician's monograph, right?

21 A. Yes.

22 Q. When did you get that?

23 A. Probably when we were training.

24 Q. Well, I want to know if you remember

1 when you got it?

2 A. Probably my training course on Prolift®.

3 Q. Well, you're saying probably --

4 A. Yeah.

5 Q. -- it sounds like you don't remember?

6 A. I don't recall the exact date, but I
7 would imagine that's about when it was.

8 Q. How did you get the monograph?

9 A. When we trained, they gave us a packet
10 of documents, and that was one of the documents.

11 Q. You think it might have been one of the
12 documents?

13 A. I think so, yeah.

14 Q. You don't recall specifically?

15 A. I think. I can't give you exact, but I
16 think, to the best of my knowledge.

17 Q. Did you think that the monograph was a
18 document that was telling you important information
19 about the risks and benefits of the Prolift®?

20 A. I felt it had tips in there on how to
21 use the mesh beyond what was in the IFU and what we had
22 learned.

23 Q. Are you aware of whether any statements
24 in the monograph are factually inaccurate?

1 A. Not offhand.

2 Q. Did you ever review the monograph to try
3 to identify those statements that might be factually
4 inaccurate?

5 A. I can't recall any factual inaccuracies
6 in the monograph. There may be if we've learned more
7 since the monograph was written that it is factually --
8 but I can't tell you at the time that it was factually
9 inaccurate.

10 Q. Would you agree with me that in terms of
11 your own knowledge of the potential risks and
12 complications with the Prolift®, that your knowledge of
13 those risks and complications increased as time went on
14 from the time you first started doing it up until the
15 time when you stopped using it?

16 A. I don't think there were any new
17 complications that I learned as I started doing
18 Prolift®. My complication rate went down as I began
19 doing Prolift® more often, but there was nothing new
20 that had happened or a complication rate that I had
21 experienced that I had not been at least aware of when
22 I started doing Prolift®.

23 Q. As you went forward in time, were there
24 publications or discussions or information that you

1 learned of about the severity of complications and the
2 impacts on some women from Prolifts® that was beyond
3 what you had known initially?

4 A. From other physicians or from my own
5 practice?

6 Q. From any source.

7 A. Not really. I mean, I know that there
8 have been, you know, significant complications, but,
9 again, in my own practice I wasn't seeing that, and,
10 you know, these are anecdotes.

11 Q. So you relied on what you read in
12 specific published literature, specific documents from
13 Ethicon and your own personal experience?

14 A. Usually.

15 Q. You made a reference -- go to Page 15,
16 if you could, and at the very bottom you talk about
17 "the primary drawback of the anterior colporrhaphy is a
18 relatively high risk of recurrent prolapse," right?

19 A. Right.

20 Q. And you talk about a reported recurrence
21 rate of over 30%, and you cite to Dr. Weber and some
22 other doctors' article, right?

23 A. Yes.

24 Q. Do you know what the findings are as to

1 what percentage of patients with a recurrence from
2 colporrhaphy actually require surgery to treat that
3 recurrence?

4 A. There's different reports on that.

5 Q. There are reports into the single
6 digits, correct?

7 A. There are some reports that are a little
8 bit higher than that.

9 MR. SLATER: Move to strike.

10 BY MR. SLATER:

11 Q. Well, let me ask you this: Maybe you
12 haven't seen all the studies. Are you familiar with
13 studies that actually find that the re-operation rate
14 for recurrence of prolapse after, for example, a
15 anterior colporrhaphy is under 10%?

16 A. There are some studies that show that,
17 yes, but it's about that number.

18 Q. I saw in your list of studies Diwadkar.
19 It's actually on your little Prolift® notes document.

20 Are you familiar with that article?

21 A. Yes, I am.

22 Q. You didn't discuss it at all in your
23 report, did you?

24 A. No, but I'm familiar with the article.

1 Q. And on your Prolift® notes, it's listed
2 on the last page, but there's no notes next to it in
3 terms of the significance.

4 A. Right.

5 Q. As you sit here right now, what does the
6 Diwadkar article discuss?

7 A. It's the re-operation complication rate
8 between native tissue and Prolift®.

9 Q. And it points out that the nature of the
10 complications and the re-operations is higher for the
11 mesh, right?

12 A. The re-operation --

13 MS. KABBASH: Objection.

14 THE WITNESS: -- rate is higher for
15 prolapse, but for recurrence it's higher for
16 native tissue.

17 BY MR. SLATER:

18 Q. Do you know what Ethicon's view is as to
19 the significance of the Diwadkar article?

20 A. I don't know what Ethicon's view is, no.

21 Q. You talk about the Lowman article, which
22 studied Prolift® dyspareunia, right?

23 A. Yes.

24 Q. Is that an important article to you?

1 A. Sure.

2 Q. 17% de novo dyspareunia, right, with the
3 Prolift®, right?

4 A. Yes, but it was high in everybody.

5 MR. SLATER: Move to strike from "but"
6 forward.

7 BY MR. SLATER:

8 Q. Do you know Dr. Lowman?

9 A. Not personally.

10 Q. Do you know Dr. Hale who also authored
11 that article?

12 A. Not personally.

13 Q. Do you know that Dr. Hale was a paid
14 consultant to Ethicon at the time the article was
15 published?

16 MS. KABBASH: Objection.

17 BY MR. SLATER:

18 Q. The Lowman article?

19 A. If you say so.

20 Q. Do you know that Dr. Lowman has worked
21 as a expert for Ethicon, paid expert? Are you aware of
22 that?

23 A. I'm a paid expert for Ethicon. It
24 doesn't change my opinions about the procedure that

1 we're talking about.

2 MR. SLATER: Move to strike.

3 BY MR. SLATER:

4 Q. Are you aware that Dr. Lowman is a paid
5 expert for Ethicon?

6 A. You're telling me that now, yes.

7 Q. You didn't know that before, right?

8 A. No.

9 Q. Go to Page 27, I guess. I don't need to
10 refer to the report, actually. Let me have a little
11 discussion with you about something.

12 You talk about the Amid classification
13 for pore size in your report, right?

14 A. Yes.

15 Q. And that's from an article he published
16 in 1997, right?

17 A. Yes.

18 Q. And he published that based on an
19 evaluation of pore sizes in hernia meshes, right?

20 A. Yes.

21 Q. And that was at a time when lightweight,
22 large pore meshes were not yet available on the market,
23 right?

24 MS. KABBASH: Objection.

1 THE WITNESS: Right.

2 BY MR. SLATER:

3 Q. And he was talking about 75 microns as
4 an adequate pore size to allow the body's defenses to
5 try to eradicate bacteria from the pores, correct?

6 A. Right.

7 Q. The Amid classification is not
8 addressing whether or not one has a risk or an
9 increased risk for bridging fibrosis or scar plating,
10 correct? It doesn't address those issues, right?

11 A. No, because these were not -- he doesn't
12 specifically use those terms, right.

13 Q. When we talk about the pore size in the
14 context of scar plate and bridging fibrosis, the size
15 that is discussed in the literature is a one centimeter
16 pore size, correct?

17 MS. KABBASH: You said centimeter.

18 MR. SLATER: I meant milliliter.

19 THE WITNESS: In the Amid classification
20 of type 1?

21 BY MR. SLATER:

22 Q. No, no, the question made no sense
23 because I said centimeters anyway.

24 Well, let me ask you this: Are you

1 familiar with the literature of Klinge, Klosterhalfen
2 and Cobb?

3 A. I've reviewed some of that literature,
4 yes.

5 Q. Do you know what they say as to what
6 a -- what the criteria is for a heavyweight, small pore
7 mesh?

8 A. No, not offhand.

9 Q. Do you know what criteria they use for a
10 midweight mesh?

11 A. I don't know the actual parameters, no.

12 Q. And you don't know the parameters for
13 what they use to qualify a lightweight, large pore
14 mesh, do you?

15 A. I don't know. I can't regurgitate those
16 parameters for you, no.

17 Q. In terms of your expertise, you wouldn't
18 hold yourself out as an expert with regard to the
19 actual materials with regard to specific pore sizes,
20 would you?

21 A. I am not a materials expert, but I'm
22 very familiar with the use of these meshes in the human
23 body and how they're placed.

24 Q. Are you familiar with literature

1 discussing the significance of a 1 millimeter pore
2 size?

3 A. No, not offhand. I mean, probably some
4 of the Moalli literature talks about that.

5 Q. Did you rely on Moalli literature in
6 forming your opinions? I saw one article mentioned.

7 A. Yeah, I'm trying to remember. I think
8 so, yes.

9 Q. The articles that she's written on the
10 subject of what happens to mesh under tension and in
11 use, I didn't see those mentioned actually in your
12 reliance list or your report? They're not there, are
13 they?

14 MS. KABBASH: Objection.

15 THE WITNESS: They're not because those
16 are sort of benchwork articles, and I prefer
17 the articles about the human body use.

18 MR. SLATER: Move to strike from
19 "because" forward.

20 BY MR. SLATER:

21 Q. Are you aware that those who design mesh
22 and actually evaluate whether mesh is going to be safe
23 and efficacious or not actually rely on studies like
24 Dr. Moalli's studies that we just talked about?

1 A. They have to because that's what we have
2 until it's implanted in the human body, but after it's
3 implanted in the human body, those kinds of articles
4 are more important.

5 Q. Well, have you studied the literature
6 regarding what the mesh characteristics are when it's
7 explanted after someone has complications? Have you
8 read that literature?

9 A. I read some of that literature, but that
10 is -- that I don't give credence to as I do as much as
11 the Level 1 evidence that shows how mesh behaves in the
12 human body over time.

13 MR. SLATER: Move to strike from "but"
14 forward.

15 BY MR. SLATER:

16 Q. Have you read articles or studies or any
17 peer-reviewed information about what happens to -- what
18 the condition of mesh is when it's been explanted from
19 patients due to complications? Have you read that
20 literature?

21 A. I have, but I find it very faulty.

22 MR. SLATER: Move to strike from "but"
23 forward.

24 BY MR. SLATER:

1 Q. The literature I just mentioned to you,
2 you did not take that into account in forming your
3 opinions, correct?

4 MS. KABBASH: Objection to form.

5 THE WITNESS: I consider it, but I just
6 don't consider it in a high level because
7 there's so many variables that come with mesh
8 explants, like how the explant is done, how
9 much tension the surgeon is applying. It can
10 deform the mesh just by taking it out.

11 BY MR. SLATER:

12 Q. Are you aware that one of the things
13 that doctors look at when they explant mesh after
14 complications, the doctors actually write these studies
15 about what it looks like, that they look to see if the
16 mesh has bridged the pores and formed scar plating and
17 whether the mesh appears to be contracted? Do you know
18 that they look at those things, or are you not aware?

19 A. They probably do, but I don't think that
20 that's so important because we don't know about the
21 patients who have these meshes inside them and whether
22 those same -- who are asymptomatic who have those same
23 phenomenon, but it's not a clinical problem for them.

24 Q. You just said they probably do. You

1 don't know whether or not. You're just saying I guess
2 it might happen, but you can't point to it?

3 MS. KABBASH: Objection to form.

4 THE WITNESS: I have read some of those
5 articles. I'm just saying why I don't find
6 them to be very reliable.

7 BY MR. SLATER:

8 Q. You didn't factor them into your
9 analysis because you reject them as having any
10 reliability?

11 MS. KABBASH: Objection.

12 BY MR. SLATER:

13 Q. Am I understanding your approach?

14 MS. KABBASH: Objection,
15 mischaracterization.

16 THE WITNESS: I say that they are not as
17 reliable as what I look to in the Level 1
18 evidence, where we see that large groups of
19 women have these implants and are doing very
20 well with them.

21 BY MR. SLATER:

22 Q. There's Level 1 evidence where some of
23 the patients have serious complications within those
24 groups, right?

1 A. But it's rare and it's really not any
2 different than the Level 1 evidence we have with other
3 types of surgeries for pelvic organ prolapse.

4 MR. SLATER: Move to strike from "but"
5 forward.

6 BY MR. SLATER:

7 Q. There's Level 1 evidence where some of
8 the patients with Prolifts® are documented to have
9 serious complications, right?

10 A. Yes.

11 Q. You've read, for example, the Prolift®
12 literature, you cited some of it in there, some studies
13 done with Prolifts®, right?

14 A. Mm-hmm.

15 Q. And you've seen complication rates
16 documented of 16, 17, even higher percentages of
17 erosion rates, right?

18 A. I have.

19 Q. Those are -- that has to be of concern
20 to anybody looking at the safety profile of the
21 product, erosion rates in excess of 15%, right?

22 MS. KABBASH: Objection.

23 THE WITNESS: It depends. It depends on
24 where in the surgeon's time frame and how long

1 they've been doing the procedure, and a lot of
2 people who have 15% erosion rates in the
3 beginning are not having those towards the end
4 of their -- later in their careers, and it also
5 depends on the type of erosion, how symptomatic
6 it is.

7 BY MR. SLATER:

8 Q. An overall erosion rate of 17% in a
9 peer-reviewed study, in and of itself is something that
10 you have to be concerned about and want to look at.

11 Would you agree with that?

12 A. I would want to look at it, but I'd want
13 to know more specifics about what those erosions were
14 and the level of severity.

15 Q. Well, you saw studies that had those
16 percentages of erosion. What did you do to try to
17 understand the significance of those findings? Let's
18 talk about Withagen, 17% erosion rate, right?

19 A. Yes.

20 Q. What did you do to study the
21 significance of the 17% erosion rate? What's your
22 analysis?

23 A. I think you can't always analyze from a
24 study what the significance of the erosion is.

1 Q. Well, 17% in and of itself is of
2 concern, correct?

3 A. Right, but not all of those patients are
4 going back to the OR to have their exposures corrected.

5 MR. SLATER: Move to strike from "but"
6 forward.

7 THE WITNESS: In fact, only 30% of
8 patients who actually had exposures go back to
9 the operating room to have them corrected. So
10 that, by definition, shows that there's a large
11 amount of asymptomatic patients who have either
12 small or asymptomatic exposures.

13 MR. SLATER: I struck from the word
14 "but" forward for all of that.

15 BY MR. SLATER:

16 Q. There are studies where more than 50% of
17 the patients with erosions have to have re-operations,
18 correct?

19 A. There is, there is one or so, but not in
20 the large meta-analyses.

21 Q. In the Withagen study with the 17%
22 erosion rate, she was a Prolift® consultant --
23 rephrase.

24 Withagen was an Ethicon consultant; she

1 was being paid by Ethicon, right?

2 A. I suppose.

3 Q. She had a 17% erosion rate, right?

4 That's what she documented in a peer-reviewed study,
5 right?

6 A. Yes.

7 Q. You would assume she was skillful,
8 right?

9 A. I don't know her.

10 Q. Did you do any evaluation of her erosion
11 rate and the erosions described in that study to
12 determine whether it was a concern to you or not? Did
13 you actually evaluate that study?

14 A. No, not specifically that study because
15 I looked at other studies. That was not just the only
16 study about exposures.

17 MR. SLATER: Move to strike from
18 "because" forward.

19 THE WITNESS: The national exposure rate
20 is about 10% in the large meta-analyses.

21 BY MR. SLATER:

22 Q. That's for all meshes for prolapse,
23 right?

24 A. For all meshes.

1 Q. Do you know what the actual -- withdraw
2 that.

3 What percentage of patients suffering
4 persistent chronic vaginal and pelvic pain after a
5 Prolift®, what percentage would be of concern to you?
6 How high does the percentage have to go before you say
7 this is something we have to be concerned about?

8 MS. KABBASH: Objection to form.

9 THE WITNESS: You're talking about de
10 novo pelvic pain?

11 BY MR. SLATER:

12 Q. Yes.

13 A. Well, we don't want to see any de novo
14 pelvic pain in any of our patients, so even one patient
15 is not something that we are happy with.

16 Q. I'm talking about persistent,
17 symptomatic vaginal, pelvic pain that's permanent and
18 is symptomatic for the patient for the rest of her
19 life, what percentage of women would need to suffer
20 that before you would say the risks outweigh the
21 benefits for this product?

22 A. But that's not been my experience with
23 Prolift® when reviewing the literature that it causes
24 symptomatic vaginal or pelvic pain more than any other

1 procedure for pelvic organ prolapse.

2 Q. This is my question: Sitting here as an
3 expert, is there any frequency of persistent, permanent
4 vaginal and pelvic pain resulting from a Prolift®
5 surgery where you would say that's too much, we
6 shouldn't use this procedure?

7 MS. KABBASH: Objection.

8 BY MR. SLATER:

9 Q. What's the percentage you'd have to get
10 to before you'd say that's enough?

11 MS. KABBASH: Calls for speculation.

12 MR. SLATER: She's an expert in the
13 case.

14 BY MR. SLATER:

15 Q. What's your opinion?

16 A. My opinion is that pelvic pain and
17 vaginal pain can happen after any procedure that we do,
18 and we must warn patients beforehand that that's a
19 possibility, but we have to weigh, like you said, the
20 risks and benefits of doing surgery versus not doing
21 surgery, and for women who are very bothered and
22 debilitated by their pelvic organ prolapse, they are
23 sometimes or more often than not willing to take the
24 risk of pelvic pain.

1 MR. SLATER: Move to strike.

2 BY MR. SLATER:

3 Q. I'm just asking you what percentage
4 would be too high to say that the benefits outweigh the
5 risks?

6 MS. KABBASH: Objection.

7 BY MR. SLATER:

8 Q. I just want to know what percentage.
9 1%? If 1% of the women were getting permanent,
10 persistent, chronic pelvic and vaginal pain that was
11 going to be symptomatic for the rest of their life, is
12 that acceptable to you?

13 A. It was something I'd have to warn the
14 patient about and let the patient and I make the
15 decision together about whether it was worth that risk.

16 Q. Okay. At 2%, if you knew 2% of the
17 patients were getting that, would you say that's too
18 much, I'm not going to use this anymore?

19 MS. KABBASH: Objection, asked and
20 answered.

21 THE WITNESS: It's an individual
22 decision between the patient and the doctor
23 where the doctor informs the patient about the
24 risks of surgery, and the surgeon and the

1 patient decide whether the risks are worth the
2 benefits of outcome.

3 BY MR. SLATER:

4 Q. If 10% of the patients with Prolifts®
5 were getting that outcome, would you still say the
6 Prolift® is still something that's reasonable to
7 recommend?

8 MS. KABBASH: Asked and answered.

9 THE WITNESS: Twenty, 30, 40, 50%, if
10 that was a common outcome, which it's not, I
11 would definitely have to let a patient know
12 that that was a debilitating possibility.

13 BY MR. SLATER:

14 Q. So at 50%, if one out of two women were
15 having that outcome, you would still say it's
16 reasonable to use this?

17 MS. KABBASH: Objection,
18 mischaracterization, asked and answered.

19 THE WITNESS: With any procedure, if the
20 risks were so high, I probably wouldn't be
21 doing it. I like my patients.

22 BY MR. SLATER:

23 Q. We'll see. You refer to abdominal
24 sacrocolpo -- rephrase.

1 You refer to a laparoscopic
2 sacrocolpopexy as a minimally invasive technique with a
3 steep learning curve on Page 30?

4 A. Okay.

5 Q. Is that accurate?

6 A. Let me see where we are.

7 Q. Bottom, five lines up.

8 A. Yes.

9 Q. On Page 31 at the bottom, you indicate
10 at the bottom, "There have been numerous studies on
11 this type of graft in the treatment of apical prolapse
12 such as ASC."

13 Now, first of all, when you talk about
14 this type of graft, you're just talking about Amid Type
15 1 mesh, right?

16 A. Yes.

17 Q. You say "the safety of this approach,"
18 meaning abdominal sacrocolpopexy, right?

19 A. Yes.

20 Q. "Has been well established in numerous
21 studies reported over the last several decades," and
22 that's accurate, right?

23 A. Yes.

24 Q. Did you use any other mesh kits besides

1 the Prolift® and Prolift+M®. You mentioned Coloplast,
2 you tried one of theirs, I think?

3 A. A few times, yes.

4 Q. Any others?

5 A. No.

6 Q. Let's look at Page 33. You mentioned in
7 the middle paragraph at the bottom, you cite a couple
8 of studies. You say Berrocal 2004 and Cosson ICS
9 abstract 2005, right?

10 A. Yeah.

11 Q. Are you familiar with that abstract or
12 those abstracts, actually?

13 A. Yeah, there's a bunch of them.

14 Q. Are you familiar with them?

15 A. I'm familiar with them, but I can't
16 regurgitate them.

17 Q. Did you see the exposure rates of I
18 believe it was about 6.7%?

19 A. Okay. You'd have to pull the study for
20 me to see for sure.

21 Q. I don't have it. I'm Rain Man with this
22 stuff. I have no life. It's what I do.

23 A. 6.7%, yes, you're right. You're good.

24 Q. Yeah, it's too bad. Too bad for me.

1 Did you see in the Cosson ICS abstract
2 that they described a 6.7% rate of exposure as high?

3 A. In the abstract, I don't recall whether
4 they qualified that as high, but that sounds about
5 right.

6 Q. Just above what I just talked to you
7 about, you talk about the decision by the TVM group to
8 choose Gynecare Gynemesh® PS.

9 Do you know how that decision was made?

10 A. You mean the inner workings of how they
11 picked their mesh?

12 Q. Right.

13 A. I don't know. Probably it had something
14 to do with the history with TVT.

15 MR. SLATER: Move to strike from
16 "probably" forward.

17 BY MR. SLATER:

18 Q. You understand that Gynemesh® PS is
19 different from the mesh in the TVT products, right?

20 A. Of course.

21 Q. You call Gynemesh® PS a low weight mesh.
22 Do you see that?

23 A. Yes.

24 Q. Are you aware of the fact that material

1 scientists, including, for example, Cobb, who is a paid
2 consultant to Ethicon would term Gynemesh® PS as a
3 midweight mesh?

4 A. Okay, but it's lower weight than the
5 original Prolene mesh was.

6 Q. When you're talking about the Prolene
7 mesh, you're talking about the mesh in the TVT?

8 A. Yes.

9 Q. That's a small pore, heavyweight mesh,
10 right?

11 A. No.

12 MS. KABBASH: Objection.

13 THE WITNESS: That's not a small pore.

14 When you're comparing the PS to the original
15 TVT mesh, it's lower weight.

16 BY MR. SLATER:

17 Q. Are you aware that, for example, Cobb
18 and Klinge, those people who actually study these
19 things, consider Prolene, the Prolene mesh and the TVT
20 to be a heavyweight, small pore mesh? Do you know that
21 they characterize it that way?

22 A. Maybe they do, but that is not how I
23 think it should be characterized.

24 Q. And that decision by you, is that based

1 on a peer-reviewed study by someone who is an expert on
2 the materials?

3 A. I had read a lot of the biomaterials,
4 and it's considered to be not a heavyweight mesh, TVT.

5 Q. Really, okay.

6 You refer to the surgical procedure
7 being refined over a five-year period through more than
8 600 surgical interventions by the nine French surgeons,
9 and that was ultimately documented in the Caquant study
10 right, 684 patients?

11 A. Yes.

12 Q. Complication rates over 30%, do you
13 remember that?

14 MS. KABBASH: Objection.

15 BY MR. SLATER:

16 Q. Do you remember that?

17 A. That number includes a lot of things,
18 stress incontinence, it includes mesh exposure. It
19 includes many, many other things.

20 Q. They documented in the Caquant study the
21 complications through three months, right, early
22 complications?

23 A. Yes.

24 Q. And they came up with a percentage, I

1 don't have it in front of me, but I believe it was in
2 excess of 30%, right?

3 That was the number they came up with
4 right?

5 A. I don't have it in front of me, but I
6 know it included a lot of things, including recurrent
7 stress incontinence.

8 Q. They termed that complication rate as
9 being a high rate of early complications, right?

10 MS. KABBASH: Objection. I'm just going
11 to continue my objection to asking the witness
12 about specifics about particular studies
13 without the report date -- excuse me -- without
14 the study being --

15 MR. SLATER: She can say she doesn't
16 know without looking at the study.

17 MS. KABBASH: That's fine. I'm just
18 going to continue my objection. Go ahead.

19 BY MR. SLATER:

20 Q. Is the answer you need to look to see if
21 I'm right?

22 A. It is. I'm just recalling that one
23 thing that we just discussed.

24 Q. Do you recall that they described the

1 early complication rate in excess of 30% at three
2 months as being high?

3 A. Again, I don't recall the exact
4 complication rate. I just remember what went into that
5 complication pool.

6 Q. Well, the rate of over 30% complications
7 at three months, that is a high rate of complications,
8 right?

9 MS. KABBASH: Objection.

10 THE WITNESS: But it depends on what
11 you're calling complications. I mean, there's
12 serious complications, there's minor
13 complications. There's someone coming back
14 with a post-operative urinary tract infection.
15 I mean, these are all things that we see with
16 any procedure to correct prolapse.

17 MR. SLATER: Move to strike.

18 BY MR. SLATER:

19 Q. Do you agree with the TVM group that
20 authored the article about their own patients that the
21 rate of over 30% complications after only three months
22 was a high rate.

23 Do you agree that's a high rate?

24 A. I agree that 30% of significant

1 complications after any procedure is a high rate.

2 Q. Do you agree that there were
3 complications at over 30% at three months was a high
4 rate of complications?

5 A. Again, it depends on what goes into that
6 complication rate.

7 Q. Do you have a over 30% complication rate
8 with your patients at three months?

9 A. It depends on what you're talking about
10 as complications.

11 Q. Any complications.

12 A. A urinary tract infection, persistent
13 pain for a few months. I mean, it depends on what goes
14 into that complication rate. It can happen.

15 Q. However you qualify your complications,
16 do you have over 30% complication rates at three
17 months?

18 A. Certainly not serious complications.

19 Q. Well, any complications. Do you have
20 over 30% of your patients with complications?

21 A. I don't consider them complications. I
22 consider them to be peri-operative healing.

23 MS. KABBASH: Dr. Fleischmann, I'm going
24 to remind you to wait until Mr. Slater gets to

1 the end of his question, okay.

2 THE WITNESS: Thank you.

3 BY MR. SLATER:

4 Q. On Page 34 you're going through the
5 history of the TVM group developing the Prolift®, and
6 in the first full paragraph you say, "The procedure
7 could be performed on women with all stages of prolapse
8 but was best suited for those with more advanced stages
9 of prolapse," right?

10 A. I'm trying to find where --

11 Q. First full paragraph, first sentence.

12 A. Yes.

13 Q. Was that your understanding of what the
14 TVM group thought was the best indication, women with
15 advanced stages of prolapse?

16 A. Yes, and I just, in general, think
17 that's the best indication for surgery.

18 Q. You cite the Prolift® Surgeon's Resource
19 Monograph, Page 3, right?

20 A. I do.

21 Q. And do you believe that the monograph
22 provides reliable information about which patients
23 would be the best patients for the procedure?

24 A. Yes, at the time that it was written.

1 Q. Did your view change at some point after
2 you read it?

3 A. No, not specifically.

4 Q. Do you believe now that it's still
5 accurate, or you think it's not accurate?

6 A. No, I believe it's accurate.

7 Q. It says in part, that in patients with
8 previous failure, that would be somebody that had a
9 prior Prolift® -- rephrase.

10 It says, in patients with previous
11 failure, that would be someone who had prolapse treated
12 previously, so this is now their second or more repair,
13 correct?

14 A. That's what that would indicate.

15 Q. Patients with risk factors for failure,
16 that would be somebody who may have a medical condition
17 or some kind of a tissue issue where you wouldn't
18 expect them to heal very well, that kind of thing?

19 A. Sure.

20 Q. And/or the most severe degree of
21 prolapse. The most severe degree of prolapse, what
22 does that mean?

23 A. It means at least a stage 3 or stage 4.

24 Q. And when you say a stage 3, you're

1 talking about a clear stage 3, not some borderline 2 or
2 3, you're talking about a clear 3 or a 4, right?

3 A. I'm talking about a 3 or a 4. It
4 doesn't mean that it couldn't be done in other
5 patients. It just means that that's the best
6 indication, that you could get away with maybe doing a
7 native tissue repair in someone who has lesser degrees
8 of prolapse. That's what that states.

9 Q. Because they say actually those are the
10 clearest indications?

11 A. Yes.

12 Q. Use the word clearest indications.
13 You agree with that?

14 A. I think so, yeah.

15 Q. Did Ethicon and the IFU ever state that
16 the clearest indications were for women with the most
17 severe degrees of prolapse who had previous failures of
18 prior surgery and had risk factors for failure?

19 Did Ethicon ever warn doctors as to that
20 patient criteria?

21 A. No, that's not in the IFU.

22 Q. It's not in the patient brochure either,
23 is it?

24 MS. KABBASH: Objection to form.

1 THE WITNESS: Patient brochure, no.

2 BY MR. SLATER:

3 Q. Did you read the patient brochures in
4 your practice?

5 A. I had them in my office, yeah.

6 Q. So you would have read them, right?

7 A. Yeah.

8 Q. You would have been familiar with what
9 they said?

10 A. Yeah.

11 Q. Okay. Did you assume that they told the
12 truth about risks and benefits?

13 A. To the best that they could, yes.

14 Q. Did you give the patient brochures to
15 your patients?

16 A. I did in the beginning. After a while I
17 stopped.

18 Q. You would just rely on your discussion?

19 A. Yes, and I had a written -- my own
20 writing that I had given to the patients based on my
21 own understanding of how the procedure went and the
22 most current literature.

23 Q. If you go to Page 35, the very bottom,
24 the last four lines it says, "Tension on the anterior

1 and posterior meshes is adjusted before removing the
2 cannulas."

3 That's an important part of the
4 procedure, right?

5 A. Yes.

6 Q. "This is performed with closed vaginal
7 wall and manual compression of the deepest portion of
8 the implant to keep the device from overtightening."

9 A. Yes.

10 Q. That's very important, from your
11 perspective?

12 A. Yes.

13 Q. You didn't want to overtighten, correct?

14 A. Right.

15 Q. Now, it's not saying no tension, and
16 it's not saying not to tighten at all. It's just
17 saying you want to get an appropriate level of tension
18 and tightness, correct?

19 A. The description is exactly as described.

20 Q. But, I mean, the answer to -- rephrase.

21 I'm correct that nowhere have doctors
22 been told there should be no tension whatsoever and no
23 tightness. It's just don't have too much tension or
24 too much tightness. That's the instruction, right?

1 A. The idea is for the implant to lay flat
2 over the tissues, but not to be under tension.

3 Q. Well, there has to be some tension to
4 keep it in place, right?

5 A. Yeah. I mean, we do pull up on the --
6 we do pull up on the straps initially, but then once
7 they're pulled up, we want to reduce that tension to a
8 very acceptable level.

9 Q. Whatever that acceptable level is,
10 there's some level of tension left on the Prolift® when
11 it's left in the body at the end of the surgery, right?

12 A. It has to be laying flat in the pelvis,
13 yes. I mean, it has to support.

14 Q. There has to be some tension?

15 A. There has to be support, yes, or else
16 there will be a failure.

17 Q. Meaning right away there would be a
18 failure?

19 A. It'd be a failure right then.

20 MR. SLATER: Let's just go off the
21 record for a second.

22 (Discussion off the record.)

23 (Brief recess taken at 12:57 p.m.)

24 (Deposition resumes at 1:35 p.m.)

1 BY MR. SLATER:

2 Q. Doctor, you talk about the patients you
3 treated with Prolift® and Prolift+M®, and you say you
4 did about 500?

5 A. Roughly.

6 Q. Okay. Obviously, initially it would
7 have only been the Prolift® because there was no
8 Prolift+M® yet, right?

9 A. Correct.

10 Q. How many Prolift®s would you say you did
11 before you started to do the Prolift+M®?

12 A. I would just have to calculate it by the
13 years, so I would probably break it down that if I was
14 doing Prolift® and M total for five years, that the
15 last two years was M, so that would be 200 out of the
16 500.

17 Q. When you say the last two years would be
18 M, you were using just the Prolift+M® the last two
19 years?

20 A. Yes.

21 Q. So there came a point when you stopped
22 using the Prolift® and were exclusively using the
23 Prolift+M®, correct?

24 A. My hospital would only let me stock one

1 product, so we were stocking the M.

2 Q. You chose the Prolift+M[®] as opposed to
3 the Prolift[®], correct?

4 A. I started doing the M by choice.

5 Q. In terms of the complications that you
6 say you saw with your patients, you don't know your
7 overall complication rates or profile because your
8 patients didn't all return to you? You don't know what
9 their outcomes were in all cases, right?

10 A. Well, all of my patients returned to me
11 postoperatively.

12 Q. In the long term you don't know what all
13 the outcomes are for your patients, correct?

14 A. I don't know every patient, but I know a
15 lot of them.

16 MR. SLATER: Move to strike from "but"
17 forward.

18 BY MR. SLATER:

19 Q. Turn to Page 39 of your report, you talk
20 about an article where the first author is Menefee,
21 M-e-n-e-f-e-e?

22 A. Yes.

23 Q. Is that Prolift[®]?

24 A. It's polypropylene mesh.

1 Q. Do you know what products were used?

2 A. Not offhand. I'd have to look at the
3 article.

4 Q. Not the Prolift®, right?

5 A. I'm not entirely sure.

6 Q. You found that this study showed that
7 there was no difference found in the composite failure
8 measures, including anatomic and quality of life
9 outcomes among the three groups, colporrhaphy, porcine
10 and mesh; that's what it says, right?

11 A. There was a lower anatomic fail rate
12 within the mesh group. Repeat the question for me.

13 Q. You say, "no difference was found in
14 composite failure measures including anatomic and
15 quality of life outcomes among the 3 groups."

16 A. In composite measures, but the anatomic
17 failure rate was higher in the other groups.

18 Q. Do you accept that anatomic failure rate
19 is less important than the quality of life and the
20 symptoms the patient reports?

21 A. I think anatomic rates are very
22 important.

23 Q. You don't operate based solely on an
24 anatomic recurrence. You operate for a recurrence if

1 there's a symptomatic component that causes quality of
2 life deterioration, correct?

3 A. That's usually what leads you to a
4 re-operation is symptomatic complaints.

5 Q. So there may be anatomic recurrences if
6 you, for example, define a recurrence as stage 2, where
7 the patient doesn't feel bothered and doesn't need any
8 further treatment, right?

9 A. Exactly, subjective is important.

10 Q. You cite at the top of Page 40, about
11 halfway through, to Haluska. You say Halsaka, but it's
12 Haluska, right? That's just a misspelling?

13 A. It's a typo.

14 Q. What was the erosion rate reported in
15 Haluska; do you remember?

16 A. I can't remember offhand, no.

17 Q. 17% or more, does that sound right?

18 A. I don't recall.

19 MS. KABBASH: Objection.

20 THE WITNESS: Yeah, no, I don't.

21 BY MR. SLATER:

22 Q. Why would you cite to just the --
23 rephrase.

24 Why would you only talk about the

1 recurrence rates in that study and not talk about the
2 erosion rate when it's in double digits, at the very
3 least?

4 MS. KABBASH: Objection to form.

5 THE WITNESS: Well, in this particular
6 paragraph, I'm talking about recurrence in
7 general, and I think recurrence rates are
8 important.

9 BY MR. SLATER:

10 Q. These are anatomic recurrence rates,
11 right?

12 A. Yes, in separate parts of this report I
13 talk about erosion, just not in this particular
14 paragraph.

15 Q. I don't remember seeing the Haluska
16 erosion rates cited anywhere. Did you cite to it?

17 A. No, but I talk about erosion rates in
18 general.

19 MR. SLATER: Move to strike from "but"
20 forward.

21 BY MR. SLATER:

22 Q. On Page 40 you talk about the Altman
23 2011 RCT, right?

24 A. Yes.

1 Q. Is that study important to you in
2 forming your opinions?

3 A. Yes.

4 Q. Did you ever look at the red lines of
5 the Altman manuscript that were done by medical affairs
6 directors at Ethicon before it was submitted to the New
7 England Journal of Medicine?

8 A. No.

9 Q. Are you aware that medical directors at
10 Ethicon red lined the manuscript before it was
11 submitted?

12 A. No.

13 MS. KABBASH: Objection to form.

14 BY MR. SLATER:

15 Q. Are you aware that editors of New
16 England Journal of Medicine were deposed with regard to
17 that article?

18 A. I'm not aware of that, no.

19 Q. I assume you haven't seen any of the
20 exhibits from the depositions of the New England
21 Journal of Medicine editors, right?

22 A. I have not.

23 Q. The Altman conclusion was that when you
24 looked at quality of life in terms of the reported

1 subjective criteria, weren't the outcomes essentially
2 there was no statistically significant difference
3 between the Prolift® and the native tissue?

4 A. No, there was a statistical significance
5 in the bulge symptoms.

6 Q. Are you sure about that?

7 A. I'm pretty sure.

8 Q. That's what you say in the report,
9 right?

10 A. I'm pretty sure, yeah.

11 Q. Did you review the appendices to the
12 Altman study?

13 A. The references or the appendices?

14 Q. The appendices in the New England
15 Journal of Medicine.

16 A. I looked at them, I'm sure.

17 Q. I asked if you read them.

18 A. I'm sure.

19 Q. Do you remember anything about that
20 data?

21 A. No.

22 Q. On Page 40 into 41 you talk about the
23 study by Sokol, et al., and you say, "the recurrence
24 rate in the posterior mesh group was 21.9% vs 18.2% in

1 the non-mesh group with no statistical significance,"
2 right?

3 A. Yes.

4 Q. So that's essentially finding whether
5 you use mesh or native tissue for posterior repair, at
6 least that study, right?

7 A. Right.

8 Q. Then you talk about Withagen, the RCT,
9 and one of the things you talk about is that if mesh
10 was used to repair a posterior prolapse, there was a
11 significantly higher rate of de novo prolapse elsewhere
12 in an untreated compartment, as opposed to if native
13 tissue was used for the prolapse repair, right?

14 A. Right.

15 Q. And that ties in with what we talked
16 about earlier that when you use this mesh to support a
17 prolapse, that there's a displacement of forces to the
18 untreated compartment?

19 A. Right.

20 Q. That puts more strain on it, correct?

21 A. Correct.

22 Q. To your knowledge, did Ethicon ever warn
23 of that in any of their documents?

24 A. No.

1 Q. And that would hold true for anterior
2 and posterior mesh, right?

3 A. No, they did not.

4 Q. Looking on Page 41 you discuss the
5 Cochrane review, and this was not limited to Prolift®.
6 This is talking about overall --

7 A. Yes.

8 Q. -- treatments, correct?

9 A. Correct.

10 Q. One of the things they found in your
11 third bullet point, "more women in the mesh group
12 required repeat surgery for the combined outcome of
13 prolapse, stress incontinence, or mesh exposure,"
14 right?

15 A. Yes.

16 Q. And that is consistent with
17 Dudcar(ph.) as well having higher re-operation rates for
18 mesh, right?

19 MS. KABBASH: Objection.

20 THE WITNESS: Exposure.

21 BY MR. SLATER:

22 Q. You said exposure?

23 A. Right, higher rates of operation in the
24 mesh group because of exposure.

1 Q. It's a complication that gets surgically
2 treated, right?

3 A. It can, if it can't be taken care of in
4 the office.

5 Q. Well, I want to talk to you about that.
6 When people talk about taking care of an
7 exposure in the office, whether it's in the office or
8 the hospital, you are still doing a surgical procedure
9 to remove mesh, right?

10 A. Not really.

11 Q. Well, you're having the woman be placed
12 on the table, you're using surgical instruments to cut
13 mesh out of her vagina, and then you are closing the
14 incision, right? It's an operative procedure, just
15 taking place in the office versus in the hospital,
16 right?

17 A. It's on the level of a Pap smear with
18 how invasive it is.

19 Q. Really?

20 A. Really.

21 Q. Do you know there are some women that
22 find it to be an incredibly uncomfortable experience to
23 be in a doctor's office under some local anesthesia
24 having mesh cut out of her vagina?

1 A. If it was that type of procedure, I
2 probably would do it in the operating room. I wouldn't
3 do anything that was too uncomfortable for a woman to
4 handle in the office.

5 Q. Well, I didn't say too uncomfortable to
6 handle because women have it done, but have you ever
7 taken the time to talk to the patients and ask them how
8 they enjoyed the experience of having mesh cut out of
9 their vagina in the office?

10 A. Yes. In fact, I find that many of the
11 patients if I've had to do that don't even remember
12 that experience because I've had conversations with
13 some of my patients and I've said, do you remember when
14 we had to remove that, and they said no.

15 Q. All right. And there's some that
16 probably do remember the experience, right?

17 A. More often than not, no.

18 Q. More often than not the patients forget
19 that you cut mesh out of their vagina in the office;
20 that's the majority of your patients?

21 A. Hasn't happened that many times, but I
22 can tell you that I have spoken to women who have been
23 through this with me, and I haven't found that to be an
24 unpleasant experience for them.

1 Q. And that's your personal experience,
2 right?

3 A. After talking to my patients, yes.

4 Q. Let's talk across the board with doctors
5 around the United States. Do you know how women
6 generally feel about the experience of having mesh cut
7 out of their vagina in the doctor's office?

8 A. I can't tell you that, but I can tell
9 you they probably would remember having to go back to
10 the operating room to repair a recurrence more likely
11 than to have a little piece of mesh cut out of them,
12 which is on the level of a suture being removed from
13 them in the office.

14 MR. SLATER: Move to strike from "but"
15 forward.

16 BY MR. SLATER:

17 Q. There is a risk that an erosion can
18 occur, it can be treated, more erosion can happen, it
19 can be treated, and it can keep happening; that's a
20 risk, right, recurrent erosions, right?

21 A. It's a small risk.

22 Q. Well, is there some study you can point
23 to that quantifies the number of what the percentage of
24 that risk is?

1 A. I can't point to a study. I can just
2 tell you that a mesh erosion, when you take it out, if
3 you take it out properly will not come back.

4 MR. SLATER: Move to strike after "I
5 can't point to a study."

6 BY MR. SLATER:

7 Q. There's no study that actually
8 quantifies recurrent erosions that you can point to,
9 correct?

10 A. Yes, but there's no study to the
11 opposite that shows that mesh erosions recur.

12 Q. Have you read the Blandon article from
13 the Mayo Clinic doctors?

14 A. No. You would have to show it to me,
15 and I can tell you if I have.

16 Q. Let's see if it's on your list. I think
17 it is. Yeah, here it is Blandon, et al.,
18 "Complications from vaginally placed mesh in pelvic
19 reconstructive surgery."

20 A. Okay.

21 Q. International Urogynecology Journal,
22 2009.

23 Do you remember that article?

24 A. No, not offhand.

1 Q. As you sit here now, is there anything
2 about that article you relied on in considering and
3 forming your opinions?

4 A. I can't remember the article offhand.

5 Q. See if I can refresh your memory. Do
6 you remember anything about -- rephrase.

7 To refresh your memory, do you remember
8 seeing in the article a picture of Prolift® mesh that
9 had been removed from the woman, do you remember seeing
10 the actual color of the mesh on gauze?

11 Do you remember that picture?

12 A. I just don't remember the article, so
13 I'm not going to remember the picture that you're
14 talking about.

15 Q. On Page 42 you talk about an SGS
16 systematic review in 2016, right?

17 A. Yes.

18 Q. Do you remember a systematic review from
19 SGS from earlier in time? Have you ever seen that
20 systematic review?

21 A. I think there was one from about 2007 or
22 '08.

23 Q. Miles Murphy authorized it; do you
24 remember that?

1 A. Yes, yes.

2 Q. Did you cite to that one?

3 A. I'm not sure. I don't think I did
4 because this is more updated.

5 Q. You said based on that study, Number 4,
6 "Mesh erosion occurred in up to 36% of patients."

7 When you refer to that you're saying
8 that was the high number you saw in one of the studies
9 that they considered in their review?

10 A. That was the high number of overall
11 outcomes.

12 Q. If anybody were to suggest that the
13 decision of whether or not a woman is going to have a
14 medical device, in this case the Prolift®, placed into
15 her body that that decision is up to the doctor and
16 that the patient doesn't play a role in making that
17 decision, you would disagree with that, right?

18 A. Of course. Well, that's the informed
19 consent process.

20 Q. And if there were a court that were to
21 say as long as the doctor says I would still have done
22 the Prolift® on this patient, even if you told me
23 additional risks, for example, let's say, I showed a
24 doctor some risks and you say it wouldn't matter to me,

1 I still would have done it, if there were a court that
2 said that's enough, it doesn't matter what the patient
3 would say because as long as the doctor says that he or
4 she would still recommend it, that's the end of the
5 inquiry, that would be divorced from what actually
6 happens in actual medical practice, correct?

7 MS. KABBASH: Objection, calls for legal
8 conclusion and beyond the scope of expert
9 opinions.

10 BY MR. SLATER:

11 Q. You can answer.

12 A. I don't really understand the question.

13 Q. I know it's hard to understand, I agree,
14 because it makes no sense, but I'll ask it again, which
15 it doesn't.

16 I'm going to give you a scenario where a
17 doctor who is an implanter is shown some risks about
18 the Prolift®, they say I wasn't aware of those risks?

19 A. Shown from whom?

20 Q. By me in the deposition. I show them
21 documents.

22 A. By a lawyer?

23 Q. Yeah, in a deposition. I show documents
24 to the implanting doctor and they say, I was not aware

1 of those risks, but I still -- even if you told me
2 those back then, I still would have recommended the
3 Prolift® to the patient, I think it would have made
4 sense for them, and I would have still said I recommend
5 this to you as a treatment and would have still told
6 the patient, look, you have other options, but I'm
7 recommending this to you.

8 If a court were to say, that's it, we
9 don't care what the patient says she would have done if
10 told these additional risks as long as the doctor says
11 they would recommend it, that's the end of the inquiry
12 as to whether or not those additional warnings would
13 have mattered or not, essentially taking the patient
14 out of the decision-making, that would not comport with
15 actual medical reality in terms of how the consent
16 process works, correct?

17 MS. KABBASH: Objection. I'm sorry, I
18 have not been making long objections. I really
19 don't think this is fair. You are --

20 MR. SLATER: Don't make a speaking
21 objection.

22 MS. KABBASH: Calls for legal
23 conclusion, calls for legal analysis.

24 MR. SLATER: No, it doesn't.

1 MS. KABBASH: You are asking her to
2 comment on the learned intermediary doctor,
3 that's not fair, beyond the scope of the
4 opinions.

5 BY MR. SLATER:

6 Q. You can answer.

7 A. I just want to ask a question.

8 Q. Sure.

9 A. You are asking me to make a legal
10 decision?

11 Q. No. I'm asking how medicine works. I
12 was saying if you compare that to how medicine works,
13 that would be because the patient has an absolute right
14 to be told whatever risks are known and then make her
15 own decision for what she wants done to her, right?

16 MS. KABBASH: Same objection.

17 THE WITNESS: I am only going to speak
18 to the fact the informed consent process is
19 what it is. It's well explained. I don't need
20 to explain it.

21 BY MR. SLATER:

22 Q. The patient has the right to be told the
23 risks that are known because she can make her own
24 decision of what she can do, right?

1 A. Yes.

2 (Brief recess taken at 1:56 p.m.)

3 (Deposition resumes at 2:41 p.m.)

4 BY MR. SLATER:

5 Q. Let's look at Page 44 and 45. You talk
6 about mesh exposure, and when you do that, you're
7 talking about exposure into the vagina, correct?

8 A. Yes.

9 Q. The first thing you say is that the
10 causes or the risk factors, rather, have not been
11 completely elucidated.

12 You're talking about in the literature?

13 A. Yes.

14 Q. There is some literature that talks
15 about what may be causing it, but there hasn't really
16 been a study that's determined what causes exposure; am
17 I correct?

18 A. I think there's no definitive study. I
19 think there's theories.

20 Q. Let's take smoking, for example.
21 Smoking is associated, in general, with wound healing,
22 right?

23 A. Exactly.

24 Q. But someone may be a smoker and their

1 wounds could heal fine, and someone could not smoke at
2 all and they could have a wound healing issue, right?

3 A. Right.

4 Q. There's also literature that says I
5 think the time period is about three weeks, if somebody
6 who is even a heavy smoker stops for three weeks
7 leading up to the surgery, that should alleviate the
8 risk.

9 Are you familiar with that?

10 A. No, but --

11 Q. You haven't seen that?

12 A. No, I haven't.

13 Q. You say that the most commonly seen, and
14 this is the third line on Page 45, "The most commonly
15 seen presentation of mesh exposure includes mesh
16 visible at a previous suture line, without any evidence
17 of inflammation/granulation and well incorporated into
18 the adjacent intact vaginal epithelium."

19 First of all, when you say it's the most
20 commonly seen, do you mean by you?

21 A. That's the most commonly seen by me.

22 Q. You're not talking about any specific
23 source of literature for that proposition, right?

24 A. Let me just look at where you are. Just

1 show me where you are, which paragraph.

2 Q. The very top of the page, the third
3 line.

4 A. Okay. Well, I do cite literature for
5 this. I mean, I do cite an article.

6 Q. Is that the sole source for that
7 proposition, or were you actually talking about your
8 own personal experience?

9 A. Well, I agree with that. That's why I
10 wrote it, from my own personal experience, but I do
11 cite that article. That it's a suture line is most
12 common.

13 Q. What's the basis to say that the most
14 common -- the most commonly seen presentation, not just
15 in your practice, but across the United States, is mesh
16 visible at the previous suture line. What would be the
17 support to say that's what is most commonly seen across
18 the board in this country?

19 A. If it's in the midline of the vagina,
20 where this incision was, as opposed to another area of
21 the vagina where no incision is made.

22 Q. No, I understand what it means.

23 A. Right.

24 Q. Here's my question: What, if any,

1 support do you have to say that that is the most
2 commonly seen presentation of mesh exposure, meaning
3 mesh visible at a previous suture line? What's the
4 source of that to tell me that's the most common
5 presentation across the country? I mean, you told me
6 what you see, that's your practice, that's not
7 necessarily everybody.

8 A. Right.

9 Q. So what's your source to say that's the
10 most common across the board?

11 A. I don't have a source besides the one
12 that I cited.

13 Q. You say, "less common presentations
14 include exposure along a vaginal sulcus."

15 And, just for the record, what does that
16 mean?

17 A. It's the crease where the vagina meets
18 the skin or the mucosa over the bone, over the pubic
19 bone.

20 Q. "Along unincised vaginal mucosa or
21 visible fibers through intact, thin epithelium."

22 Those are three what you call less
23 common presentations?

24 A. Yes.

1 Q. Is that based on your own experience?

2 A. Yes and, also, I think this is from this
3 record that I cite.

4 Q. The Wu article?

5 A. Yes.

6 Q. Exposure into the vagina can occur not
7 at the suture line, correct?

8 A. It can.

9 Q. That can be associated with clear signs
10 of inflammation, correct?

11 A. I don't really know how to answer that.

12 Q. Have you ever treated an exposure into
13 the vagina not at the suture line with a Prolift®?

14 A. Yes.

15 Q. Okay. The tissue in those cases can be
16 inflamed, correct?

17 A. I mean, not necessarily. I guess -- I
18 don't know how to answer inflammation. I mean,
19 inflammation to me means red and irritated and
20 purulent, and we don't really see that with exposures.

21 Q. You define inflammation to include
22 purulent, which is a sign of an infection?

23 A. It can, but I don't see that with these
24 exposures.

1 Q. When you said inflammation you associate
2 with being purulent, that's --

3 A. I just said it could mean that. I don't
4 mean that it is definitely associated with that.

5 Q. I mean the term inflammation, you can
6 have inflammation in response to an infective process,
7 but you can also just have inflammation completely
8 unassociated with any infection whatsoever, right?

9 A. Yes.

10 Q. Are you aware of whether or not scar
11 plating, bridging fibrosis of the mesh itself can lead
12 to an increased risk and cause erosion?

13 A. I don't really have an opinion about
14 scar plating or bridging fibrosis in terms of erosion.

15 Q. You say, I'm continuing in the same
16 paragraph on Page 45, the middle of the page, "Here
17 perforation of the sulcus by the implantation needles
18 (or trocar), 'button-holing' of the epithelium during
19 dissection or progressive epithelial thinning due to
20 urogenital atrophy are likely the primary causes."

21 What are you citing for that statement?
22 What are relying on to say that?

23 A. I am relying on my own experience and
24 several articles that I have read that have

1 corroborated that.

2 Q. Mesh exposure, as you're describing, can
3 occur without any of those things occurring, right?
4 Meaning, you can have mesh exposure where there's no
5 perforation of the sulcus by the implantation needles,
6 where there's no button-holing of the epithelium during
7 dissection and where there's no progressive epithelial
8 thinning due to urogenital atrophy, right?

9 A. You could.

10 Q. You would have to look in an individual
11 case at what occurred to that person if you wanted to
12 try to form an opinion as to the cause in that
13 patient's case, right?

14 A. You would.

15 Q. You can do a full thickness dissection,
16 and you can still get an exposure into the vagina,
17 right?

18 A. Very unlikely.

19 Q. Are you telling me that from a
20 theoretical perspective, or are you saying there's been
21 some study that has shown that it's not going to
22 happen? I mean, I want to understand.

23 A. I think that when you look at the
24 studies of people who have been doing procedures like

1 Prolift® over time, as we get better and better at
2 doing the full thickness dissection, we watch our
3 erosion rates go down, and that's because we've learned
4 to do proper full thickness dissections.

5 Q. You were taught to do the full thickness
6 dissection that you said brought your exposure rate way
7 down by Dr. Lucente, right?

8 A. Yes, he clued me into it.

9 Q. Did he seem to know how to do a full
10 thickness dissection?

11 A. Yes.

12 Q. He taught you how to do it, right?

13 A. He showed me, and then I also learned
14 about it reading about Prolift® in the monograph.

15 Q. When he showed you, did his technique
16 seem to be correct?

17 A. I really can't remember. I just
18 remember discussing it with him.

19 Q. Vincent Lucente taught you the full
20 thickness dissection, right?

21 A. Yes, he explained to me how it was done,
22 and I learned it from that.

23 Q. What would you expect the erosion rate
24 into the vagina or the exposure rate, if you want to

1 call it that, should be for somebody who's doing a
2 proper full thickness dissection with a Prolift®?

3 A. Under 3%.

4 Q. Do you know what Dr. Lucente's erosion
5 rate into the vagina is?

6 A. I know from the initial study it was
7 higher.

8 Q. Do you know what it was for his own
9 patients in his clinical practice? Let me ask the
10 question --

11 A. He'd probably say it was 0%.

12 Q. Let me -- well, he probably would.

13 Would you believe that if he said he had
14 zero erosions?

15 A. No, I would not, I would not.

16 Q. What would you expect -- well, you know
17 what, there was a question I asked. Let me ask it
18 again, can you just tell me what I said. I want to
19 make sure I don't miss something here. It was like
20 three questions ago.

21 (The court reporter read back the record
22 as follows:

23 "Question: Do you know what it was for
24 his own patients in his clinical practice?")

1 BY MR. SLATER:

2 Q. Do you know what Dr. Lucente's exposure
3 rate or erosion rate, whatever you want to call it,
4 into the vagina was with his own patients in his own
5 clinical practice?

6 A. During what years?

7 Q. During any years.

8 A. During the last few years he was using
9 Prolift®?

10 Q. During any of the years he was using
11 Prolift®.

12 A. But it changes, it changes as we get
13 better.

14 Q. Doctor, I don't want to argue with you
15 about whether it changes. I didn't ask you if it
16 changes. I want to start broad.

17 Do you know what Dr. Lucente's exposure
18 rate was at any time for his own patients in his own
19 practice?

20 A. I only know about his initial article.

21 Q. His initial article being what, which
22 article?

23 A. It was high, it was about 12%, 13%.

24 Q. What's his initial article? Which one

1 are you talking about?

2 A. The Lucente Miller article was a 14%
3 exposure rate.

4 Q. Are you talking about the TVM study?

5 A. The TVM study.

6 Q. That wasn't the Prolift®, was it?

7 A. No, it's not.

8 Q. So let's talk about the Prolift® now.
9 Do you know what --

10 A. No, I don't know the number offhand.

11 Q. Do you know during any time period what
12 Dr. Lucente's erosion was for Prolift®, his own
13 practice?

14 A. No, I do not know.

15 Q. But you testified if someone is doing it
16 the right way with a full thickness dissection, it
17 should be under 3%, right?

18 A. It should be.

19 Q. And you haven't seen the analysis that
20 was done of his internal data through the ISS grant by
21 Ethicon, right?

22 A. No, I have not seen that analysis.

23 Q. Just coming back, and I don't know what
24 you said to this, so if I'm repeating the question, I

1 get a demerit, you do agree that someone can do a
2 proper full thickness dissection and they can still
3 have an erosion through the vaginal tissue into the
4 vagina, right?

5 A. Yes, because it's for a different
6 reason. Like, there could be a suture disruption or a
7 hematoma behind the vagina that creates a suture
8 disruption, and you could still get an exposure that
9 way.

10 Q. You can also have a chronic inflammatory
11 reaction that causes damage to the tissue and leads to
12 the mesh eroding through the tissue, right?

13 A. I don't know. I haven't really seen
14 that in my practice.

15 Q. Okay. I understand you haven't seen it
16 in your practice.

17 Do you have an opinion one way or the
18 other as to whether that happens?

19 A. I think it's conjecture about whether it
20 happens. I don't know clinically whether it happens.
21 I don't know how we could tell that that was happening.

22 Q. I just want to know if you have an
23 opinion whether that's something that happens to some
24 patients?

1 A. I think there are more other likely
2 reasons why someone might have an exposure than that.

3 MR. SLATER: Move to strike.

4 BY MR. SLATER:

5 Q. My question is whether you have an
6 opinion one way or the other whether that occurs,
7 erosion through the vagina where someone did a proper
8 full thickness dissection?

9 A. When there is a suture disruption or a
10 hematoma, yes.

11 Q. Okay. How about when there's no suture
12 disruption or hematoma?

13 A. No suture disruption, no hematoma, no
14 faulty pass?

15 Q. Right.

16 A. Very unlikely.

17 Q. Well, what are you basing that on?

18 A. I'm just basing that on 500 Prolifts®
19 that I've done and basing it on the literature that
20 I've read.

21 Q. Do you have an opinion one way or the
22 other as to whether or not there can be scarring of the
23 mesh that then leads to erosion through the tissue,
24 even if there was a proper full thickness dissection?

1 Can that happen?

2 A. I don't think that we could say it was
3 from that. I don't know how someone would say what
4 caused the exposure.

5 Q. I just want to know if you -- so you're
6 saying it doesn't happen or it can, or you don't know?

7 A. I don't think it could be known that --
8 I'm sorry, I'm jumping on it.

9 MS. KABBASH: Just want to remind you to
10 wait until he's completely finished before you
11 start your answer.

12 THE WITNESS: I think that if there's a
13 mesh exposure and it's not at the area of the
14 suture line, it's somewhere else, that it could
15 or in more cases than not, it would have to be
16 because of a faulty dissection, not a full
17 thickness dissection.

18 MR. SLATER: Move to strike.

19 BY MR. SLATER:

20 Q. Here's my question: Can there be a mesh
21 erosion as a result of the mesh being scarred and scar
22 plated coming through the tissue, even if there was a
23 full thickness dissection properly done? Do you have
24 an opinion of whether or not that can happen or no

1 opinion?

2 A. I don't have an opinion about that.

3 Q. Okay. Have you read -- I know you've

4 done a lot of expert work now in this litigation.

5 You've been an expert I assume in a bunch of cases

6 where people were -- in individual cases, right?

7 A. I've done some. I don't know what a

8 bunch is, a lot is.

9 Q. Well, have you done more than ten

10 Prolift® cases where you've looked at people's records

11 and seen what happened to them?

12 A. No.

13 Q. Let's talk about your report, Page 46,

14 your heading "Contraction."

15 First of all, I want to understand, do

16 you agree that contraction occurs with the Prolift®,

17 the Prolift+M® and Gynemesh® PS?

18 A. I think that it's been described. I

19 don't really always understand what it means when we

20 say "contraction."

21 Q. So you don't have an opinion as to

22 whether or not it occurs. You say it's described, but

23 you're not telling us you have an opinion one way or

24 the other of whether it occurs?

1 MS. KABBASH: Objection.

2 THE WITNESS: I'm just telling you I
3 don't really understand the full definition of
4 contraction in a symptomatic way.

5 BY MR. SLATER:

6 Q. Have you read medical literature that's
7 talked about contraction for symptomatic patients?

8 A. Yes.

9 Q. Having read that, though, you still
10 don't understand what they're talking about?

11 A. I understand what they're talking about,
12 but I don't know how they diagnose it. I think
13 everybody has a different definition of a mesh
14 contraction.

15 Q. Do you know how the doctors in the TVM
16 group diagnosed contraction?

17 A. No, and I've been trying to figure that
18 out because when they say that they had a such and such
19 rate of mesh contraction, they really don't explain
20 what that means.

21 Q. You read all their articles?

22 A. I read it, but it's hard for -- I'm
23 still not getting a good definition of how they said
24 this person has a retraction versus that person has a

1 retraction.

2 Q. Have you read literature about doctors
3 palpating through the tissue mesh that was hard and
4 rigid and caused pain when it was being touched? Are
5 you aware that that happens with some patients?

6 A. I'm aware of feeling mesh through
7 tissues, but I can't always say that it causes pain
8 when it's being touched.

9 Q. I didn't say "always," I never said the
10 word "always."

11 Are you aware of what I just described
12 to you, reports of doctors palpating in the vagina,
13 feeling hardened, thickened mesh behind the vaginal
14 tissue?

15 A. Yes.

16 Q. And that when they press on it or
17 palpate it, it causes pain for the patient?

18 A. Yes, I've heard of that, but I am also
19 aware of mesh that feels contracted behind the vaginal
20 wall that doesn't cause any symptoms in the patient
21 that you can palpate and the patient doesn't feel any
22 symptoms.

23 Q. So you would agree that contraction in
24 some cases can be clinically symptomatic?

1 A. I guess if you feel and you palpate an
2 area that's hard and it hurts the patient, then it is
3 symptomatic, and I more likely than not feel that it's
4 under too much tension.

5 MR. SLATER: Move to strike the "and I
6 more likely than not" part at the end.

7 BY MR. SLATER:

8 Q. One of the risks with the Prolift®
9 procedure is that excessive tension would be left on
10 some or all of the mesh leading to complications;
11 that's one of the risks, right?

12 A. Yes, it is.

13 Q. And in the scenario where excessive
14 tension is left on the mesh, that can cause the pores
15 to be condensed down and lead to scar plating; that's
16 recognized, right?

17 A. I guess theoretically, yes.

18 Q. When there's tension on the mesh,
19 particularly the arms of the Prolift®, that can lead to
20 tension banding of the arms, correct?

21 A. I'm not really sure. I mean, I think if
22 you put any part of the mesh under too much tension,
23 whether it's the arms or the body, that you could feel
24 an area of the mesh under the vaginal wall. The thing

1 is it's not always clinically felt by the patient,
2 which is why it's hard to know the clinical
3 significance of it.

4 MR. SLATER: Move to strike "the thing
5 is" part at the end.

6 BY MR. SLATER:

7 Q. On Page 46 where you're talking about
8 contraction and you point out the 2011 FDA warning, the
9 FDA thinks contraction occurs, right, because they
10 mention it as a risk, right?

11 A. Yes, it's a risk, the FDA knows about
12 it.

13 Q. Do you have an understanding of the
14 understood quantification of contraction with Prolift®
15 mesh?

16 MS. KABBASH: Objection.

17 THE WITNESS: I don't have an
18 understanding of the clinically significant
19 contraction with Prolift® mesh.

20 BY MR. SLATER:

21 Q. Okay. Do you know what level of
22 contraction Ethicon expected to occur with the Prolift®
23 inside the body?

24 A. Probably about 30 to 40%.

1 Q. Did you ever see where it said 30 to
2 50%?

3 A. I mean, this just goes back to the
4 hernia data.

5 Q. Well, I'm going back to the
6 understanding of the Prolift®.

7 Did you ever see any internal documents
8 that talked about an expected contraction rate of 30 to
9 50% of the mesh?

10 A. I've seen it that high, yes.

11 Q. You in this on Page 46, talking about
12 contraction, cited to Amid, an article from 1972
13 regarding "A simple stapling technique for the
14 prosthetic repair of massive incisional hernias,"
15 right?

16 A. Yes.

17 Q. And he was talking about -- and that's
18 what you cited for 20 to 30%, that's where that
19 statistic came from, right?

20 A. Yes.

21 Q. Then you cited another article about
22 hernia, "Inguinal hernia advances or controversies?"
23 Right?

24 A. Yes.

1 Q. You then go down a little further and
2 you say "Dietz et al. found no evidence of mesh
3 contracture in 40 patients who underwent anterior TVM
4 repair using translabial 4-dimensional ultrasound,"
5 right?

6 A. Right.

7 Q. And that's the article we talked about
8 earlier that's not about the Prolift®, it was about the
9 Perigee, correct?

10 A. We discussed that.

11 Q. On Page 47 you have a chart of
12 dyspareunia rates based on a series of articles.

13 Were those the most important articles
14 to you in addressing the dyspareunia rates?

15 A. They were many of them, yeah.

16 Q. Were there any others that you would add
17 to the chart right now, if you could?

18 A. Let's see. I don't have the Dietz on
19 there. Unless -- oh, I have it there. It's just not
20 on this specific chart, but it's also -- it's in the
21 report.

22 Q. I'm talking about the chart, any other
23 important studies. You say Dietz, that's Dietz and
24 Maher.

1 A. Yeah, Dietz is the meta, so it's just
2 discussing these studies anyway.

3 Q. Is that the Dietz that you cite to on
4 Page 48, Dietz and Maher?

5 A. Yes.

6 Q. Where you say they "also found no
7 difference in sexual function between anterior repairs
8 with and without mesh"?

9 A. That's the one.

10 Q. When you refer to sexual function, what
11 are you referring to?

12 A. I'm referring to the studies that did
13 questionnaires. I mean, they're all in the randomized
14 controlled studies.

15 Q. Okay. But when it refers to sexual
16 function, what does that mean?

17 A. It's pain, it's dyspareunia, pain.

18 Q. In your chart you didn't list the Altman
19 RCT, which you said was very important to you, did you?

20 A. No, I didn't.

21 Q. Do you know what the dyspareunia rates
22 were there, de novo dyspareunia?

23 A. Did they discuss dyspareunia in Altman?

24 Q. They did, 7% for the Prolift®, 2% for

1 the suture repairs.

2 A. Oh, there you go. But I don't think
3 they were statistically significant differences.

4 Q. The rate with the Prolift® was three
5 times as much; that would be clinically significant,
6 right?

7 A. But not statistically significant.

8 MR. SLATER: Move to strike.

9 BY MR. SLATER:

10 Q. 7% for the Prolift®, which is more than
11 3% -- rephrase.

12 The Prolift® dyspareunia rate in Altman
13 was 7%, which is more than three times the 2% for the
14 suture repair. Is that clinically significant?

15 A. But you're looking at a very small
16 percentage of patients. You're looking at 400
17 patients, so it's significant for that study
18 clinically, but not statistically.

19 MR. SLATER: Move to strike.

20 BY MR. SLATER:

21 Q. Is that answer, yes, it's clinically
22 significant?

23 MS. KABBASH: Objection.

24 THE WITNESS: But it's not statistically

1 significant.

2 MR. SLATER: Move to strike.

3 THE WITNESS: Yes, it's clinically
4 significant and not statistically significant
5 in such a small group of patients.

6 MR. SLATER: Move to strike the "not
7 statistically significant in such a small group
8 of patients" at the end.

9 BY MR. SLATER:

10 Q. Do you know what language was removed
11 from the Altman manuscript before it was submitted to
12 the New England Journal of Medicine at the request of
13 medical affairs at Ethicon?

14 MS. KABBASH: Objection.

15 BY MR. SLATER:

16 Q. Do you know what language they took out
17 regarding dyspareunia?

18 A. I don't.

19 Q. When one looks at the concept of de novo
20 dyspareunia, it's not enough to just say somebody had
21 discomfort with sexual relations after surgery to fully
22 understand what happened with that patient; would you
23 agree with that?

24 MS. KABBASH: Objection to form.

1 THE WITNESS: I don't really understand
2 the question.

3 BY MR. SLATER:

4 Q. Good. I'm doing my job.

5 With regard to de novo dyspareunia, one
6 thing you look at is the very basic thing after the
7 surgery, did the woman have discomfort with sexual
8 relations; that's kind of the general question, right?

9 A. After surgery, yes, that's the question.

10 Q. Now, after surgery you would expect
11 every woman to have dyspareunia for some period of time
12 because she had an operation through her vagina, so you
13 would expect sexual relations to be uncomfortable,
14 regardless of what type of surgery is done, right?

15 A. For a period of time.

16 Q. And then over time, for most women,
17 their surgical area heals, they get better, and they
18 don't have dyspareunia or discomfort with sexual
19 relations going forward due to the surgery, right?

20 A. Yes, over time.

21 Q. And, for example, with a suture repair,
22 over time you expect the incision to heal, you expect
23 whatever scarring there is to soften and become no
24 longer painful, right?

1 A. Right, unless they develop scar tissue
2 or they have a foreshortened vagina due to cutting out
3 the vaginal wall from, say, a vaginal hysterectomy or
4 too much of an anterior colporrhaphy cutting out the
5 vaginal wall, sometimes they can get just a narrowing
6 or tightening of their vagina that way.

7 MR. SLATER: Move to strike "unless."

8 BY MR. SLATER:

9 Q. If a woman has, due to a suture repair,
10 some tightening of the vagina, that can be released,
11 you can release the sutures, right?

12 A. No, not always, not when the vaginal
13 wall has been resected. Sometimes they don't have
14 enough vagina left to have sex. We see that.

15 Q. So that one instance is there's so much
16 tissue taken out that the woman just has very little
17 vagina left, and it's just going to be uncomfortable
18 because her vagina is so small?

19 A. And short.

20 Q. And short that it's just not going to be
21 compatible with normal relations?

22 A. Exactly.

23 Q. Okay. Where a woman has a normal size
24 vagina, not shortened, and she's had a suture repair,

1 you expect the incisions to heal over time and for the
2 woman to not have dyspareunia long term, correct?

3 A. Well, yeah, one would hope, but it still
4 happens.

5 Q. For most women, that's the course they
6 get better, right? They heal and they don't have
7 dyspareunia long term?

8 A. But that's not what the studies show.

9 Q. If they don't have a shortened vagina?

10 A. That's not what the studies show. When
11 we look at studies on any vaginal surgery, there's a
12 risk of postoperative de novo dyspareunia on any
13 procedure, whether it's a suture repair or not.

14 Q. I get that, but now I'm trying to talk
15 about why it's happening and trying to figure out those
16 women that might have it as a persistent condition, why
17 that would be?

18 A. It could be muscular, they could
19 develop -- you know, after pelvic surgery some people
20 develop pelvic floor myalgia, just from being operated
21 on in that area.

22 Q. What percentage of women with nonmesh
23 surgery develop pelvic floor myalgia due to a suture
24 repair of prolapse? Is there any study that's actually

1 analyzed that?

2 A. There may be, I don't know it though.

3 Q. Okay. Prolift® surgery and the
4 placement of the Prolift®, that can trigger a myalgia
5 situation, correct?

6 A. I think that any surgery that goes
7 through the retropubic space or the vagina or the deep
8 muscles of the vagina, whether it's a sacrospinous
9 ligament fixation or it's a deep paravaginal repair can
10 cause a pelvic floor myalgia, it's not just Prolift®.

11 MR. SLATER: Move to strike.

12 BY MR. SLATER:

13 Q. With a Prolift® one of the things that
14 happens is you operate through the obturator area,
15 correct?

16 A. You are dissecting into that area
17 exactly.

18 Q. And pulling mesh arms through it, right?

19 A. You're placing them through it.

20 Q. And then the mesh is left there after
21 the surgery is over, right?

22 A. There are straps that are left there,
23 yes.

24 Q. And before the surgery, that would not

1 have been an area that had any issues, most likely,
2 because the obturator is not part of what you would be
3 operating on with nonarm, nonmesh surgery, right?

4 A. Well, if you were doing certain
5 surgeries, like deep paravaginal repairs, anterior
6 repairs, you would get into that same space.

7 Q. You would get on the edge of it; you
8 wouldn't be putting something all the way through it?

9 A. You wouldn't put anything through the
10 muscles of the thigh.

11 Q. What I'm driving at is when you do a
12 Prolift® surgery, there's mesh left in areas where
13 there's been tracks made by the trocars in areas that
14 can lead to pelvic floor myalgia due to that trauma,
15 correct?

16 A. I suppose it's possible, but I don't
17 think that it's any greater than any other procedure
18 that we do on the pelvic floor, so I don't see that
19 that is a definite correlation.

20 Q. Well, it would be greater than with a
21 colporrhaphy, where you don't operate in that part of
22 the body, right? Because by definition if you're not
23 going there, you're not going to cause a problem there
24 with an alternative procedure, right?

1 A. Well, I feel like with a colporrhaphy
2 you're going through the deep muscles of the pelvis, if
3 you're doing it properly and you're really plicating
4 that tissue from side wall to side wall, as you should
5 be, you can absolutely get a pelvic floor myalgia.

6 Q. Do you have patients that you trigger
7 pelvic floor myalgia in when you do suture repairs?

8 A. Posterior repairs, sometimes.

9 Q. Not anterior?

10 A. Not as much with anterior repairs but
11 with posterior repairs we do.

12 Q. How often?

13 A. It's happened. I mean, not often, but
14 it happens.

15 Q. Well, how many times?

16 A. I can't give you a number on that. It's
17 just something that I see in my practice.

18 Q. How often?

19 MS. KABBASH: Asked and answered.

20 THE WITNESS: I really can't give you a
21 number.

22 BY MR. SLATER:

23 Q. How many times have you seen it with an
24 anterior repair?

1 A. I don't do a lot of anterior repairs, so
2 I can't tell you that, but I can tell you that with my
3 posterior repairs, I will see a fair amount of pelvic
4 floor myalgias afterwards.

5 MR. SLATER: Move to strike from "but"
6 forward.

7 BY MR. SLATER:

8 Q. If you see pelvic floor myalgia after a
9 suture repair, generally that resolves with time,
10 right?

11 A. Unfortunately, not always.

12 Q. I didn't say always, did I? I said
13 generally it resolves with time, right?

14 A. We hope so. We have to work with them.
15 We have to teach them how to dilate sometimes. We have
16 to give them estrogen. We have to give them things
17 that help them sometimes. It's not always a
18 cut-and-dry situation where it will get better with
19 time.

20 Q. When the mesh from the Prolift® is left
21 inside the body, do you understand that it has a
22 chronic inflammatory reaction that continues when the
23 mesh is left in the body; do you understand that?

24 A. I understand there's a graft host

1 reaction, which is chronic.

2 Q. And that plus potentially tension with
3 the mesh, potentially contraction, potentially erosion,
4 those things can cause or exacerbate myalgia, correct?

5 A. I suppose if there's tension,
6 absolutely.

7 Q. It is difficult, and in many patients
8 likely impossible, to safely or effectively remove the
9 arms of the Prolift® if you need to due to
10 complications, right?

11 A. It can be done. I've done it. It's
12 generally unnecessary.

13 MR. SLATER: Move to strike.

14 BY MR. SLATER:

15 Q. In some patients the benefit of trying
16 to remove the arms of the Prolift® to treat
17 complications would be outweighed by the risk, correct?

18 A. Right.

19 Q. And I'm talking about patients who are
20 symptomatic.

21 A. Right.

22 Q. Where the arm is causing pain but the
23 doctor says, look, I don't think that it's worth trying
24 this because I can cause a lot more damage, I think you

1 have to live with the pain, I think the surgery is too
2 risky; that is a potential scenario, right?

3 MS. KABBASH: Objection.

4 THE WITNESS: Where the arm is causing
5 pain?

6 BY MR. SLATER:

7 Q. Yes.

8 A. I haven't really seen the arm cause
9 pain.

10 Q. You, as an expert in this case, have not
11 seen any indications that the arms of the Prolift®
12 cause pain for patients?

13 A. Not typically. It's usually that
14 there's --

15 Q. Didn't ask typically.

16 You, as an expert for Ethicon on the
17 Prolift®, are you testifying to a reasonable degree of
18 medical certainty that you're not aware of the arms of
19 the Prolift® causing pain for patients, yes or no?

20 A. Not the arms in and of itself.

21 Q. Okay. Are you aware what Ethicon thinks
22 on that question of whether the arms of the Prolift®
23 can cause pain for a patient?

24 A. I'm not aware of what Ethicon thinks.

1 Q. Did you ever think it might be a
2 reasonable thing for you to want to educate yourself on
3 what Ethicon knew about the Prolift®, Gynemesh® PS and
4 the Prolift+M® to understand, based on all the
5 different sources of information coming into them, what
6 did they have available to them to see if maybe they
7 knew about things that you weren't aware of or maybe a
8 severity or a frequency of complications you just
9 didn't fully appreciate? Did you consider that?

10 MS. KABBASH: Objection to form.

11 THE WITNESS: I did try to educate
12 myself on those things.

13 BY MR. SLATER:

14 Q. I'm talking about through Ethicon's
15 knowledge, to learn Ethicon's knowledge.

16 A. I'm saying that I did try, I just maybe
17 didn't succeed in every area, but I did read expert
18 depositions, and I did try to go through some of those
19 documents.

20 Q. But I think, as you sit here now, you've
21 confirmed for me you don't really have an understanding
22 of what Ethicon's understanding is as to the risk
23 profile for the Prolift®, other than what they've put
24 in their documents?

1 MS. KABBASH: Objection.

2 BY MR. SLATER:

3 Q. That are like the IFU, the patient
4 brochure, the monograph, those types of documents,
5 other than that you don't know what they internally
6 understood, correct?

7 MS. KABBASH: Objection.

8 THE WITNESS: I have somewhat of an
9 understanding of what they understood prior to
10 going to launch with the product.

11 BY MR. SLATER:

12 Q. Is it your understanding that
13 Ethicon's -- rephrase.

14 As you sit here now, do you believe,
15 based on what you've seen, that Ethicon's understanding
16 of the risks of the Prolift® when they went to launch,
17 that they put those into the IFU so that doctors would
18 be warned of what they knew?

19 A. I think that they put enough of what was
20 known at the time of the complication risk profile into
21 the IFU so doctors could understand.

22 Q. I don't know if you're answering my
23 question directly, so I want to try to make it very
24 clear. I'm not asking about whether it was, you

1 know -- whether doctors could figure it out and all
2 that stuff.

3 My question is very direct. Did Ethicon
4 set forth the risks that it understood to exist with
5 the Prolift® when they went to the market in 2005, did
6 they set forth those risks in the IFU? Their internal
7 knowledge, was it set forth in IFU as to the risks?

8 MS. KABBASH: Objection.

9 THE WITNESS: I think that they were,
10 yes.

11 BY MR. SLATER:

12 Q. Did the IFU for the Prolift® warn that
13 retraction of the Prolift® mesh could create a risk of
14 discomfort with sexual relations with sexually active
15 women, was that warned of in the IFU?

16 A. It warned of contraction. It didn't
17 specifically talk of sexual relations in the original
18 IFU.

19 Q. Did Ethicon indicate in the initial IFU
20 or any of the IFUs that the risk of contraction of the
21 mesh and pain with sexual intercourse could be
22 increased with hysterectomy?

23 A. That is not in the IFU. It is in the
24 surgeon's monograph, though.

1 MR. SLATER: Move to strike "it is"
2 forward.

3 BY MR. SLATER:

4 Q. Do you know what the circulation of the
5 monograph was? Do you know who it was given to?

6 A. It was given to surgeons who were
7 training on Prolift®.

8 Q. Do you know during what time period and
9 to how many doctors it was given?

10 A. I don't know those numbers. I know they
11 distributed it as widely as they could.

12 Q. You just made a statement, I know they
13 distributed it as widely as they could.

14 Who told you that?

15 A. It's just a -- I just remember seeing
16 the monograph. I remember seeing it when I was
17 training.

18 Q. So you saw it?

19 A. I saw it.

20 Q. You don't know who else did, right?

21 A. Well, people that were training saw it,
22 people who were going through Prolift® training all saw
23 it.

24 Q. Well, you don't know what people saw at

1 training seminars that you weren't at, do you?

2 A. No, but I'm assuming that they stuck to
3 the same protocol as they did with me.

4 MR. SLATER: Move to strike from "but"
5 forward.

6 BY MR. SLATER:

7 Q. Do you know how many Prolift® monographs
8 were printed?

9 A. No, I don't have that information.

10 Q. You don't know how many doctors were
11 given the monograph, do you?

12 A. I don't know.

13 Q. When you first were trained on the
14 Prolift, you were already using Gynemesh® PS regularly
15 in your practice, right?

16 A. Yes.

17 Q. Go to Page 49, please. There is a
18 sentence under "Pelvic pain," the second sentence says,
19 "In most cases, postoperative pain resolves
20 spontaneously and can be managed conservatively,"
21 correct?

22 A. Yes.

23 Q. And that's true for suture repairs,
24 correct?

1 A. Mm-hmm, yes.

2 Q. Are you saying that that is true for the
3 Prolift®?

4 A. That is true for the Prolift®.

5 Q. Are you saying that's true for Gynemesh®
6 PS?

7 A. That's true for Gynemesh® PS, but that
8 doesn't always happen. I mean, we do have prolonged
9 pain with some of those patients.

10 Q. Are you saying that is true for the
11 Prolift+M®?

12 A. Any procedure for pelvic organ prolapse
13 can cause prolonged pain.

14 Q. Do you know when it was -- rephrase.

15 Are you aware of whether the TVM group
16 was asking Ethicon to put a safer mesh in the Prolift®
17 from the time even before the Prolift® went on the
18 market?

19 A. I've heard some reports that people were
20 considering other meshes.

21 Q. My question is are you aware that the
22 TVM group was asking Ethicon to use a safer mesh than
23 the mesh that was in the Prolift® even before it went
24 on the market?

1 MS. KABBASH: Objection.

2 THE WITNESS: I've been made aware of
3 that from some of the reviews that I've done.

4 BY MR. SLATER:

5 Q. Reviews of what?

6 A. Depositions.

7 Q. So you've seen it related by other
8 witnesses in a deposition?

9 A. Yes.

10 Q. Ultimately, Ethicon determined to use
11 Ultrapro mesh in the Prolift®, and they marketed that
12 as the Prolift+M®, correct?

13 A. Yes.

14 Q. Am I correct that the reason they did
15 that is because the expectation was that with the
16 Monocryl, which would absorb, that you would be left
17 with a lighter weight, larger pore mesh within the
18 human body?

19 A. That was the thinking behind it.

20 Q. Do you have an opinion as to whether or
21 not that panned out in actual clinical reality?

22 A. I think when we look at the studies, it
23 probably didn't. I can tell from you my own practice
24 that by the time I was using M, my exposure rates were

1 very low, but I really did attribute that to my level
2 of experience at that point.

3 I also felt that appreciation of the
4 implant behind the vaginal wall was much less with the
5 M than it was with the Prolift® PS, but in terms of
6 patients' happiness or outcomes, I didn't see much of a
7 difference.

8 Q. When you say appreciation behind the
9 vaginal wall, you mean being able to palpate on the
10 vaginal tissue and feel that the mesh was behind it?

11 A. Exactly.

12 Q. Did Ethicon perform any studies before
13 launching the Prolift+M® to support the claims they
14 were making to doctors as to the better outcomes they
15 could expect?

16 A. I think those were studies were in
17 progress, and they were -- I mean, I think that's where
18 they were at that point.

19 Q. Would you agree Ethicon should have
20 conducted at least a midterm, I won't even go for long
21 term, at least a midterm, year to two years I'll define
22 it as for purposes of this question, study of the
23 Prolift+M® before making claims to doctors and patients
24 that it could have or it would have improved outcomes

1 for patients?

2 A. I mean, listen, it's always good to have
3 more data before you launch something, but I think that
4 they had enough data that they felt comfortable
5 launching it, and, ultimately, there were theoretical
6 improvements with M, although, again, outcomes were not
7 different, like you said.

8 MR. SLATER: Move to strike from "but"
9 forward.

10 BY MR. SLATER:

11 Q. The Prolift+M[®] clinical study that
12 Ethicon did, tell me if I'm wrong, I think it had an
13 erosion rate of 14.8%; does that sound right?

14 MS. KABBASH: Objection.

15 THE WITNESS: Let me look at my notes,
16 if I even have it in there.

17 The Milani study was the original one,
18 that was 10% exposure rate. 10%, same as the other.

19 BY MR. SLATER:

20 Q. Was there a Prolift+M[®] study --
21 rephrase.

22 The clinical study that was used to
23 launch the Prolift+M[®], do you know what the exposure
24 rate was in that study? Are you saying that was 10%?

1 A. I thought that was the Milani study, but
2 I could be wrong. I thought that was the original
3 Ethicon-sponsored study.

4 Q. I'm looking at your notes, because you
5 brought me there, gives me something to read.

6 A. Okay.

7 Q. Under Prolift+M® you list long-term
8 studies.

9 One year is not long term, is it?

10 A. No, it's not as long as we would like.

11 Q. Three years would not be a long-term
12 study for a permanent implant, would it?

13 A. Well, no, not compared to other studies
14 that we have on permanent implants, it's not.

15 Q. So there's no long-term studies of the
16 Prolift+M®, right?

17 A. No, we never got there.

18 Q. You list Lensen, L-e-n-s-e-n, 2013, you
19 wrote, less exposure with M but likely due to author
20 experience two and a half to three and a half pore
21 size.

22 That's what you wrote, right?

23 A. Mm-hmm.

24 Q. Were those the conclusions by the

1 doctors that did that study, or is that your
2 conclusion?

3 A. That's my conclusion. I think that the
4 main conclusion was that there was less exposure rate
5 with M, but they also attributed that to their
6 technique.

7 Q. You wrote two and a half to three and a
8 half pore size. That's millimeters, right?

9 A. Yes, not centimeters. The whole thing
10 would fall through.

11 MR. SLATER: I have a mutual motion to
12 strike after the word yes on that. I was
13 sitting here thinking to myself we all know
14 that, and I realized this deposition may be
15 used by people that are never going to meet any
16 of us, may meet you, but won't me and Maha, so
17 I just thought I'd say that for the record.
18 Some people don't get humor out of the
19 transcript. We could have gotten it if Maha
20 wanted the video here, but she doesn't like
21 humor to come across.

22 MS. KABBASH: I'm a very boring person.

23 MR. SLATER: I would not agree with
24 that.

1 BY MR. SLATER:

2 Q. Okay. So the reference to two and a
3 half to three and a half millimeter pore size, that was
4 your sense of one of the reasons why there was less
5 exposure.

6 Am I reading that correctly?

7 A. You know something, I think I was just
8 trying to remind myself what the pore size was for the
9 M once the Monocryl dissolved.

10 Q. Okay. So you weren't -- even though it
11 says due to author experience two and a half to three
12 and a half pore size?

13 A. I think that was just a note I was
14 making for myself because these are my notes.

15 Q. Do you know what happened with the
16 recurrence rates of the Prolift+M[®] as compared to the
17 Prolift[®]?

18 A. Like I said, they have been about the
19 same.

20 Q. As far as an alternative to the
21 Prolift[®], the Prolift+M[®], from your perspective, was a
22 reasonable alternative once Ultrapro was placed into
23 that system, right?

24 A. It was.

1 Q. I want to talk about dyspareunia a
2 little bit with the Prolift®.

3 If a woman has discomfort or pain with
4 sexual relations as a result of the mesh from the
5 Prolift® becoming scar plated, hard, contracted, behind
6 or next to the vagina such that if you palpate on it,
7 it hurts, it's reasonable to then make an effort, if
8 deemed safe enough, to try to remove that mesh, right?

9 A. If that's what she wants. She won't
10 always want that.

11 Q. Well, one choice would be I'll live with
12 the pain or try to have physical therapy and see if
13 they can soften the scarring?

14 A. Right, exactly.

15 Q. Which is enormously painful when
16 somebody has physical therapy through the vagina
17 palpating on a painful scar band; that can be very
18 painful, right?

19 A. I suppose.

20 Q. Let's say a woman wants to have the mesh
21 removed and the doctor thinks that's a reasonable
22 alternative and actually offers it as an option, the
23 mesh may be removed or at least whatever the doctor can
24 get to, and the woman may still have that pain, right?

1 A. It's possible, especially if there is a
2 pelvic floor myalgia causing the pain from the
3 beginning and they need to do physical therapy after
4 that.

5 Q. It can be that the scar plating and
6 contraction of the mesh can cause pain at that
7 location, and it also can trigger spasm within the
8 pelvic floor as a result of that pain, right?

9 A. It could, yes.

10 Q. And that could lead to myalgia, correct?

11 A. Yes.

12 Q. And even if you remove the mesh, the
13 myalgia can remain, correct?

14 A. Well, it usually gets better after you
15 take out an area that's tense. Like, if you can point
16 to a patient having a thickened area and if you palpate
17 it and it hurts them, by removing it, you will
18 significantly reduce the discomfort. Whether there is
19 some remaining myalgia left, physical therapy --

20 Q. When you say usually -- I'm paraphrasing
21 what you said they usually get better, are you relying
22 on any study for that, or is that just your experience?

23 MS. KABBASH: Objection.

24 THE WITNESS: That's my experience, but

1 there's also studies.

2 BY MR. SLATER:

3 Q. Which study?

4 A. I can't think of offhand which study,
5 but I can tell you there are other studies which have
6 shown that removing pelvic mesh, not in everybody, but
7 in many patients will relieve the symptoms.

8 Q. In some patients you can remove the
9 Prolift® mesh in one area and the woman can feel better
10 for a period of time and pain can come back; that
11 happens to some women, right?

12 A. I guess, but this is all very
13 theoretical for me. This is not something that I can
14 say that I'm seeing a great deal of in practice. I
15 suppose if it happened, you know, yes, it could, people
16 could have complicated cases of pain after a procedure
17 like Prolift® or really, I mean, frankly any procedure
18 for pelvic floor prolapse.

19 MR. SLATER: Move to strike from "or"
20 forward.

21 BY MR. SLATER:

22 Q. One of the risks of the Prolift® is that
23 the mesh will contract around the vagina and cause
24 vaginal shortening, correct?

1 A. I suppose that it could, yes.

2 Q. Did Ethicon warn of that risk?

3 A. It warns of contraction.

4 Q. Did Ethicon warn that contraction of the
5 mesh can lead to vaginal shortening?

6 A. Well, I think that that just kind of --
7 that follows. I mean, when we think about what
8 contraction is, we're thinking of a shortening of the
9 vagina.

10 Q. When you think about -- rephrase.

11 Ethicon marketed the Prolift® and said
12 there would be some contraction with the scarring that
13 would go in through the pores, this beautiful lattice,
14 the scar net, that was supposed to be a good thing,
15 right?

16 MS. KABBASH: Objection.

17 THE WITNESS: I call that integration.

18 You're talking contraction or over-shortening
19 of the mesh.

20 BY MR. SLATER:

21 Q. I'm actually talking about terminology.

22 Ethicon told people there would be
23 in-growth of scar tissue, and it would help to create a
24 scar net and good support, and there would be some

1 contraction and that would be a good thing, right?

2 A. But they also warn, for instance, in the
3 IFU that there's a risk of contraction. I think
4 they're talking about something different than what
5 you're just describing.

6 Q. All right.

7 MR. SLATER: Move to strike.

8 BY MR. SLATER:

9 Q. Limit it to my question.

10 A. Okay.

11 Q. I'm correct that was part of what
12 Ethicon was telling doctors, right; that contraction
13 and the scarring growing through the lattice of the
14 mesh was a good thing, it was to create support, right,
15 a strong, durable support, right?

16 A. I'm just troubled because in the adverse
17 sections they talk about cracks, so, obviously, they
18 wouldn't list it in the adverse reactions if it was a
19 good thing.

20 Q. Really, they wouldn't give conflicting
21 messages?

22 MS. KABBASH: Objection.

23 BY MR. SLATER:

24 Q. Really, because it wouldn't be -- it

1 wouldn't be a good thing for Ethicon to give
2 conflicting information about something that could
3 happen with the Prolift®, on one hand saying it would
4 be a good thing, on the other hand saying it's a
5 potential risk, because that could be confusing to a
6 doctor?

7 MS. KABBASH: Objection, form.

8 THE WITNESS: I think we get a lot of
9 information from Ethicon. We understand what
10 integration and graft host relations are. We
11 understand there is tissue integration into the
12 graft. We don't want there to be an
13 over-buildup of fibroblast causing mesh to
14 contract, but that is a risk of the procedure
15 which they warn about.

16 BY MR. SLATER:

17 Q. Ethicon said in the IFU scarring that
18 leads to implant contraction, right; that's actual
19 phrase, right?

20 A. Yes, yes, yes.

21 Q. They didn't talk through how with the
22 Prolift®, this, quote, unquote, revolutionary device,
23 they described it as how they would specifically impact
24 the patient due to the Prolift® being in the body, they

1 didn't actually go through that explanation, did they?

2 MS. KABBASH: Objection to form.

3 THE WITNESS: They didn't, because I

4 still think it's questionable about how

5 symptomatic that process is for women.

6 BY MR. SLATER:

7 Q. If Ethicon thought it could be

8 symptomatic for women and believed that before they

9 even put the Prolift® on the market, they should have
10 warned about that, correct?

11 MS. KABBASH: Objection.

12 BY MR. SLATER:

13 Q. If that's what their information showed?

14 A. But they did warn of contraction.

15 Q. I'm talking about the consequences of
16 it. If they knew those consequences could be

17 symptomatic and could be difficult for the woman, for
18 example, chronic dyspareunia that wouldn't go away,

19 vaginal shortening, tension banding, those types of
20 things, they should have talked about it if they knew
21 those were risks. They should have let doctors know
22 that so they could share that with patients.

23 MS. KABBASH: Objection.

24 THE WITNESS: I'm saying that I feel

1 they did discuss those risks with us by saying
2 don't make the mesh too tight, this can cause
3 contraction. All these things we were aware of
4 when we started using these products. It's not
5 like I wasn't aware of them.

6 MR. SLATER: Move to strike.

7 BY MR. SLATER:

8 Q. Is the answer to my question, yes, that
9 they should have warned about that if they knew it?

10 MS. KABBASH: Objection.

11 THE WITNESS: Yes, and I'm glad they
12 did.

13 MR. SLATER: Move to strike from "and".

14 BY MR. SLATER:

15 Q. Look at Page 52. Put your glasses back
16 on.

17 A. I know, I thought we were done.

18 Q. I'm going to make 30 minutes feel like
19 30 years.

20 Halfway down Page 52 you actually talk
21 about the study of the Prolift+M®, right?

22 A. Yes.

23 Q. And at 3 years follow up, anatomical
24 success, meaning just measuring the location of the

1 organs, was about 75, 76%, right?

2 A. Yes.

3 Q. And mesh exposure rate was 14.8%, right?

4 A. Yeah, it's interesting, I have different
5 numbers here, but that's correct in this report. Oh,
6 this is the three-year, I apologize.

7 Q. One year was 10%?

8 A. Right, right.

9 Q. So just to be clear, at one year from
10 the Prolift+M[®] study, the exposure rate was 10%, and at
11 three years it was up to 14.8%, right?

12 A. Yes.

13 Q. Do you know if when they calculated
14 14.8%, they included exposures that occurred and were
15 counted in the earlier years and that may have been
16 treated. Do you know if they included all -- on a
17 cumulative basis all exposures -- let me ask the
18 question clean.

19 When they counted the 14.8%, did they
20 count those on a cumulative basis, meaning every
21 exposure that occurred during those three years?

22 A. I don't believe those were new
23 exposures, 14.8%, I believe those included the 10%.

24 Q. It should have included all the

1 exposures that occurred over the three years?

2 A. Yes.

3 Q. That's the proper way to count, right?

4 A. Right.

5 Q. On Page 55 you start listing Medical
6 Society statements, and on Page 57, if you go through
7 that, you say, "I strongly agree with these
8 statements."

9 So you strongly agree with those things
10 you cited in those three pages?

11 A. Yes.

12 Q. Let's look at Page 55 and 56. We have
13 the ACOG, AUGS joint recommendations, right?

14 A. Right.

15 Q. And the second bullet point at the top
16 of Page 56 says, "Pelvic organ prolapse vaginal mesh
17 repair should be reserved for high risk individuals,"
18 that's one of the statements, right?

19 A. Right.

20 Q. And that would mean somebody that's
21 likely already failed a primary repair, has risk
22 factors for failing future repairs, correct?

23 A. I also think it's somebody with a high
24 grade prolapse.

1 Q. I was going to get to that.

2 A. Okay.

3 Q. Somebody with a clear stage 3 or stage
4 4, correct?

5 A. Correct.

6 Q. And that's, from your perspective, the
7 proper criteria for the use of the Prolift® and
8 Prolift+M®, correct?

9 A. Yes.

10 Q. Also for Gynemesh® PS?

11 A. Yes.

12 Q. The fourth bullet point, "Compared with
13 existing mesh products and devices, new products should
14 not be assumed to have equal or improved safety and
15 efficacy unless clinical long-term data are available,"
16 and you agree with that, right?

17 A. Yes.

18 Q. And that would apply to the Prolift®
19 when it first went on to the market, right?

20 A. Well, we didn't have long-term data on
21 Prolift® then.

22 Q. So that principle which you applied to
23 was not adhered to with the Prolift®, right?

24 MS. KABBASH: Objection.

1 THE WITNESS: Well, the ACOG statement
2 was written after Prolift® already had some
3 long-term data on it, so they're just saying
4 that newer products need to be better
5 evaluated.

6 BY MR. SLATER:

7 Q. This principle, as far as you're
8 concerned, would apply to the Prolift® when it first
9 went on the market in 2005. They just didn't have
10 long-term studies at that time, right?

11 A. No, we had TVM study then.

12 MS. KABBASH: Objection.

13 BY MR. SLATER:

14 Q. That wasn't the Prolift®, right?

15 A. No, but I mean with the exception of the
16 placement of the product, it was the same.

17 Q. Do you know that -- do you know what the
18 endpoints were for the TVM study, the endpoints on the
19 proposal for the study? Did you ever read the proposal
20 for the TVM study?

21 A. You mean what they were looking at, what
22 they were -- safety, efficacy?

23 Q. What they were studying, do you know
24 what the primary endpoint was for the TVM study?

1 A. No. What do you mean "the primary
2 endpoint"?

3 Q. Do you know what a proposal is for a
4 clinical study?

5 A. Yes.

6 Q. Did you ever read it?

7 A. I read the TVM study. I don't know if I
8 read the proposal for it.

9 Q. Do you know what the endpoints were for
10 the TVM study?

11 A. I'm not sure what you mean. We're
12 looking at safety and efficacy of the product.

13 Q. But do you know specifically what the
14 endpoints were in terms of what they were measuring,
15 what they were looking to prove?

16 A. They were looking to prove recurrence
17 rates.

18 Q. Do you know what the endpoint was with
19 the confidence intervals applied that they deemed
20 success or failure of a study?

21 A. I've been told.

22 Q. What have you been told?

23 A. They were looking for a 20% or under
24 recurrence rate.

1 Q. Are you aware that the French TVM study
2 failed that endpoint?

3 A. I'm aware that it was unclear whether it
4 failed that endpoint. There was good data to say that
5 the recurrence rates were less, but at the highest
6 point the recurrence rate was over that 20% mark.

7 Q. Do you know who Scott Ciarocca is?

8 A. He was the R&D guy at the time.

9 Q. Bingo. Do you know what he said in
10 sworn testimony about whether the endpoints -- the
11 primary endpoint of the 20% recurrence rate was met or
12 not?

13 A. I haven't read his testimony.

14 Q. Have you ever looked at the internal
15 documents regarding whether the endpoint was met?

16 A. I've been made aware of this issue.

17 Q. The reason I'm asking is because you
18 said there was some sort of lack of clarity or
19 something or it was unclear so I'm trying to figure out
20 why you would say that when I questioned Mr. Ciarocca
21 multiple times and he has admitted to me in sworn
22 testimony it didn't meet the primary endpoint?

23 MS. KABBASH: I'm going to object.

24 BY MR. SLATER:

1 Q. So I'm curious you haven't seen that
2 testimony.

3 MS. KABBASH: I'm going to object. The
4 testimony is not before the witness.

5 Go ahead, you can answer.

6 MR. SLATER: That's my point.

7 MS. KABBASH: That's my point.

8 THE WITNESS: I can't speak to his
9 testimony. I can just tell you that after
10 reviewing some information about that, that I
11 felt that when Ethicon made the decision to go
12 forward, they felt that it was close enough and
13 that there was enough benefit from the product
14 to go forward with it.

15 BY MR. SLATER:

16 Q. Is there some document you can point to
17 where someone actually said even though we failed this
18 endpoint, we're still going to go forward because we
19 got close enough?

20 A. No, I can't point to that document.

21 Q. I'm going to tell you I've spent years
22 on this, I've never seen such a document.

23 Have you seen some witness who said
24 that?

1 A. Well, I did read Dr. Owens' testimony.

2 Q. And you think she said that?

3 A. I think she felt there was enough
4 benefit from the TVM study to go forward, yes.

5 Q. So you think it was her decision that
6 even though they failed the primary endpoint that they
7 should go forward anyway?

8 MS. KABBASH: Objection,
9 mischaracterizes.

10 THE WITNESS: I think when they looked
11 at the confidence intervals they found it was
12 an outlier that kept them from going forward,
13 and they decided to look at the main data from
14 that study.

15 BY MR. SLATER:

16 Q. An outlier you mean an outlier patient?

17 A. That there was -- yes, that there was --
18 there was an outlier result.

19 Q. Okay. What are you relying on for that?
20 I've never seen that. I'm curious. Can you point me
21 to somewhere on your reliance list what document that
22 was?

23 A. I'm talking Owens' testimony.

24 Q. She said there was an outlier patient

1 and that was the reason why they decided to go forward,
2 even though they failed the primary endpoint?

3 A. Not an outlier patient but had to do
4 with the confidence intervals of the study, that they
5 weren't tight enough. I'm telling you what I remember
6 from reading from the testimony, but from wherever it
7 was, the decision was made there was enough benefit
8 from the product to go forward.

9 Q. We fell into the rabbit hole talking
10 about long-term studies. You will agree with me the
11 TVM study was not the Prolift®, right?

12 A. Right.

13 Q. And you agree with me it failed the
14 primary endpoint if you look at the data? If you look
15 at the actual data, it failed the primary endpoint,
16 correct?

17 MS. KABBASH: Objection to form.

18 THE WITNESS: I remember it was slightly
19 off.

20 BY MR. SLATER:

21 Q. It failed the primary endpoint. The
22 recurrence rate was over 20% when they applied the
23 statistical model, correct?

24 A. I believe it was off, yes.

1 Q. And it then climbed in the following
2 years; you know that, right? The recurrence rates went
3 up and the erosion rates went up as well; you know
4 that, right?

5 MS. KABBASH: Objection.

6 BY MR. SLATER:

7 Q. When they continued to follow the
8 patients, do you know that?

9 A. The five-year data?

10 Q. I'm not talking five years. I'm saying
11 let's go from one year to two years to three years to
12 four years to five years, whatever, the rates continue
13 to go up.

14 A. You have to show me the study.

15 Q. Do you know?

16 A. No, I don't know offhand.

17 Q. The last bullet point halfway down Page
18 56 says, "Patients should provide their informed
19 consent after reviewing the risks and benefits of the
20 procedure as well as discussing alternative repairs."

21 That you absolutely agree with, right?

22 A. Yes.

23 Q. And that comes back to what we discussed
24 earlier, the decision of whether or not to have the

1 operation is the patient's, correct?

2 A. Right, with the doctor explaining to
3 them what the risks are.

4 Q. The doctor explains the risks, the
5 benefits, the alternatives, the doctor will likely
6 provide recommendations, but, ultimately, the patient,
7 in her own judgment, based on her own assessment of
8 that information, decides what to do with her own body,
9 correct?

10 A. Yes, but more likely than not the
11 patient will ask the doctor what they think should be
12 done, and the doctor will have to make a
13 recommendation.

14 MR. SLATER: Move to strike from "but"
15 forward.

16 BY MR. SLATER:

17 Q. A doctor should never be coercive,
18 right, in making a recommendation, right? Meaning if
19 the patient is asking for recommendations, the doctor
20 can give them but shouldn't actually be coercive?

21 A. Well, if you mean coercive, the doctor
22 should push the patient to do what is best for the
23 patient, then, yes, the doctor should be coercive.

24 Q. In making a recommendation?

1 A. Well, the doctor knows better than the
2 patient about these procedures and their outcomes. So
3 if a doctor thinks that a specific procedure is very
4 good for a patient, then the patient will often defer
5 to the doctor on what that -- what that procedure is.

6 Q. If the doctor consenting a patient for
7 Gynemesh® PS, for the Prolift® or Prolift+M® was not
8 given the information that Ethicon knew about the
9 risks, such that some severe risks were not disclosed
10 to the doctor, then the doctor -- and the doctor didn't
11 give that to the patient, the patient was not put in
12 the position to give fully informed consent, right?

13 MS. KABBASH: Objection.

14 THE WITNESS: If that was the case, but
15 I'm not saying that was the case.

16 MR. SLATER: Move to strike from "but"
17 forward. I just want you to know I don't like
18 saying move to strike.

19 MS. KABBASH: I know you used to
20 complain at the very beginning of the
21 litigation it was not New Jersey practice, then
22 you got very good at it.

23 MR. SLATER: No, it is New Jersey
24 practice, that is my view, you have to do it.

1 BY MR. SLATER:

2 Q. You agree that roping and curling of the
3 arms of Prolift® occurs, right?

4 A. I don't know.

5 Q. No opinion on that?

6 A. Of the arms?

7 Q. Yes.

8 A. I have no way of knowing that.

9 Q. Have you watched the surgical videos
10 that Ethicon created and used as part of their
11 professional education?

12 A. Way back when I did.

13 Q. Did you ever see evidence of roping or
14 curling in any of those videos?

15 A. Roping or curling of the arms, the arms
16 sit inside the patient. Unless we're cutting the
17 patients open, we can't see roping and curling of arms.

18 Q. Do you know what the medical affairs
19 director at Ethicon thinks about whether or not -- I'll
20 ask you, David Robinson, do you know what he thinks
21 about whether the arms are roped or curled inside the
22 body?

23 A. No, I don't know what Dave Robinson
24 thinks.

1 Q. He was a very experienced Prolift® user,
2 he was part of the TVM study, right?

3 A. I suppose he was.

4 Q. Do you know what Charlotte Owens'
5 background was? You read her deposition before she
6 became medical director. Did you see what her
7 background was?

8 A. Gynecologist.

9 Q. Pretty much a general gynecologist,
10 right?

11 A. Yes.

12 Q. Were you surprised that somebody like
13 that with only four years of general gynecology
14 experience was put in the position of worldwide
15 director for Ethicon to make decisions should we warn
16 about the Prolift®?

17 MS. KABBASH: Objection, beyond the
18 scope.

19 MR. SLATER: It's not beyond the scope.
20 She is giving opinions about Ethicon's
21 negligence claims in these cases.

22 BY MR. SLATER:

23 Q. What do you think about that?

24 A. I was not in a position at that point to

1 judge whether somebody was or was not appropriate for
2 that job.

3 Q. As you sit here right now, you read her
4 deposition recently, wasn't in time to get on your
5 reliance list, but you read it. Somebody with that
6 level of experience, you would agree, you would hope
7 that Ethicon would have had somebody far more
8 experienced in that position when they're going to
9 market with something like the Prolift® and they need
10 to have somebody overseeing clinical studies, design
11 control, all these different things that were going on,
12 right?

13 MS. KABBASH: Objection, beyond the
14 scope.

15 THE WITNESS: I'm sure she was more than
16 qualified to make those decisions.

17 BY MR. SLATER:

18 Q. Really?

19 A. I'm sure.

20 Q. Why?

21 A. Because they hired her.

22 Q. So de facto because Ethicon hired her,
23 she must have been qualified for the job?

24 A. I'm sure there were many others looked

1 at and she was picked, and I was not privy to that
2 information, so I really can't answer that.

3 Q. All the things I'm sure of, you actually
4 don't know those things?

5 A. How could I?

6 Q. I want to -- I can make it clearer for
7 the record.

8 You don't have any idea how they decided
9 to hire her, right?

10 A. Of course not.

11 Q. But they did hire her four years out of
12 her residency in general gynecology, admitted she
13 didn't even have a deep understanding of the use of
14 mesh at all, right?

15 MS. KABBASH: Objection.

16 BY MR. SLATER:

17 Q. Correct?

18 MS. KABBASH: Beyond the scope.

19 BY MR. SLATER:

20 Q. It's what she admitted, right?

21 A. I don't think that she was a pelvic
22 floor surgeon at that time, but she did claim that she
23 had used mesh products and that she was introduced to
24 those products in her residency.

1 Q. She actually also testified when mesh
2 was used, she would watch someone else use it and she
3 wouldn't use it in the operations, right?

4 A. She did work with somebody else when she
5 had to do a mesh procedure.

6 Q. You would agree with me that Ethicon
7 needed to have a fully qualified pelvic floor surgeon
8 with extensive knowledge of mesh in that position to be
9 a responsible medical device manufacturer going to
10 market with something like the Prolift®, wouldn't you?

11 MS. KABBASH: Objection, beyond the
12 scope. Dr. Fleischmann is not opining on
13 Ethicon personnel procedures and policies.
14 Beyond the scope.

15 BY MR. SLATER:

16 Q. You can answer. We disagree?

17 A. Look, I think that if they felt she was
18 a qualified person and she surrounded herself with
19 people that she had felt could help her make those
20 decisions, then I think it's just like Donald Trump.

21 Q. I'm not even going to move to strike
22 that one.

23 MS. KABBASH: I might move to strike
24 that one.

1 BY MR. SLATER:

2 Q. Was it your understanding that Charlotte
3 Owens surrounded herself with people and they worked
4 well as a team together; was that your understanding?

5 A. I understand there is a team involved
6 for everything that happens.

7 Q. Do you know about the disputes and
8 issues she had with her co-workers?

9 A. I do not.

10 Q. Every time you throw one of these I
11 assume things, you realize you open the door to all
12 this other mishegoss that comes out.

13 On Page 58, the first full paragraph you
14 say, "Nor does the medical literature provide evidence
15 that the use of Gynemesh® PS results in excessive
16 contraction of tissues causing complications to the
17 patient in the absence of overtensioning or failure to
18 ensure that the mesh is lying flat."

19 That's what you wrote, right?

20 A. Yes.

21 Q. And you were referring specifically to
22 the medical literature regarding Gynemesh® PS, right?
23 That's what you say here right, the literature?

24 A. Yeah, I'm just trying to look at where

1 you are. Okay.

2 Q. You are referring to the medical
3 literature regarding Gynemesh® PS, right?

4 A. Yes.

5 Q. And then you cite Dietz, which is an
6 article about the Perigee, which is a different
7 product, right?

8 A. Yes.

9 Q. You don't cite Velemir, which is
10 actually a study of the Prolift® with regard to
11 contraction of Prolift®?

12 A. I did not cite that one.

13 Q. You say towards the bottom of this
14 paragraph, "If mesh contraction exists, it is unlikely
15 to be a progressive phenomenon and is probably limited
16 to the period of physiological wound healing."

17 You cite Dietz again for that, right?

18 MS. KABBASH: Just to be clear, that's a
19 quote from Dietz. That's not her language.

20 BY MR. SLATER:

21 Q. I understand you are citing Dietz for
22 that, right?

23 A. Yes.

24 Q. Do you know if Dietz was being paid by

1 AMS when he published that article?

2 A. He may have been.

3 Q. Little bit of an issue, huh? You're
4 sitting talking about how great something is and you're
5 being paid by the company?

6 MS. KABBASH: Objection, harassing.

7 THE WITNESS: Only if you think the
8 person changed their data because of being paid
9 by.

10 BY MR. SLATER:

11 Q. Did you ever see any of Dietz's other
12 studies where he found there is contraction of mesh on
13 ultrasound? Did you ever see those?

14 A. No.

15 Q. You should look and see.

16 MS. KABBASH: Do you have them for her
17 because I've been asking for that all day? Do
18 you have that?

19 MR. SLATER: I don't have anything.
20 I've got what you got, I have Post-it notes.

21 MS. KABBASH: My standing objection
22 continues.

23 MR. SLATER: Who is giving documents?
24 That doesn't work for me. I am a solo guy on a

1 horse.

2 MS. KABBASH: James will be very happy
3 to hear.

4 MR. SLATER: He will be very happy to
5 know he wasn't helping me with this, believe
6 me.

7 BY MR. SLATER:

8 Q. Do you actually -- when you say that --
9 rephrase.

10 You cited Dietz. Were you saying that
11 this description of what he says with regard to the
12 Perigee, which is a different mesh and different
13 product, were you trying to say this would apply to the
14 Gynemesh® PS?

15 A. I'm talking about mesh in general, yeah.

16 Q. So when we go back through it, you
17 actually can't say that those quotes throughout your
18 report from Dietz actually specifically apply to the
19 Prolift® or Gynemesh® PS, right?

20 MS. KABBASH: Objection.

21 THE WITNESS: I think there is a paucity
22 of literature, good literature on mesh
23 contraction in general, so we have what we
24 have.

1 BY MR. SLATER:

2 Q. What is the periodic -- rephrase.

3 What is the period of physiologic wound
4 healing?

5 A. Well, it has to do with, you know, the
6 four stages of wound healing and mesh incorporation.

7 Q. What is the period of physiological
8 wound healing; how long is that? Trying to get an
9 idea, you cited this.

10 A. I have to go back to the graft, probably
11 about three to four months.

12 Q. So it's your assumption that contraction
13 stops happening after three to four months, or you're
14 just saying that's what Dietz said?

15 A. That's what Dietz said.

16 Q. Do you have an opinion one way or the
17 other on that?

18 A. I think that the healing happens, and
19 that's when we see the mesh incorporation and what it's
20 going to be, about three or four months.

21 Q. Do you know whether -- rephrase.

22 Do you have an opinion as to whether
23 contraction of the mesh, Gynemesh® PS, the Prolift®,
24 Prolift+M®, whether that continues after three or four

1 months, do you have an opinion on that?

2 A. I think it may, but I don't know that
3 it's symptomatic.

4 Q. It may be, it may not be; you don't
5 know?

6 MS. KABBASH: Objection.

7 THE WITNESS: I think more likely than
8 not, it's not symptomatic.

9 BY MR. SLATER:

10 Q. Why do you say that?

11 A. Because we have large meta-analysis of
12 data that do not talk about mesh contraction or do not
13 talk about what you so call the effects of mesh
14 contraction are.

15 Q. Do you know in those studies whether
16 they were looking for mesh contraction?

17 A. No, but they're looking at other things
18 like dyspareunia and recurrence and all the things you
19 feel would be a clinical result from mesh contraction,
20 and I don't think they exist in high levels.

21 MR. SLATER: Move to strike after "no."

22 BY MR. SLATER:

23 Q. One of the clinical manifestations of
24 mesh contraction would include vaginal or pelvic pain,

1 right?

2 A. If you believe that. I don't know that
3 that's the case. I think that mesh contraction can
4 exist without any pelvic pain or dyspareunia, and I
5 think there are studies that show that.

6 Q. Do you have an opinion, yes or no, that
7 mesh contraction can cause pelvic pain and vaginal
8 pain?

9 A. I think it can when mesh is
10 overtightened.

11 Q. Okay. Do you have an opinion as to
12 whether contraction of mesh -- I'm talking about
13 Gynemesh® PS, the Prolift® and the Prolift+M® here, I
14 don't want to talk about the rest of the world, so my
15 question is do you have an opinion as to whether
16 contraction of Gynemesh® PS, Prolift® or Prolift+M® can
17 cause dyspareunia?

18 A. I think it can, yeah, in certain cases.

19 Q. Do you agree that contraction of
20 Prolift®, Gynemesh® PS or Prolift+M® can cause
21 recurrence?

22 A. It could.

23 Q. At the bottom of Page 59 you make a
24 statement. You talk about your vast review of the

1 medical literature.

2 Did you do a vast review of the medical
3 literature?

4 A. I really tried to.

5 Q. We have pointed out some articles that
6 you didn't have in your reliance list during the course
7 of this deposition.

8 A. Yes.

9 Q. And we pointed out other articles that
10 you don't cite or discuss in your report, correct?

11 A. There are articles that I have not
12 reviewed, but that doesn't mean I haven't done a vast
13 review of the medical literature.

14 MR. SLATER: Move to strike from "but"
15 forward.

16 BY MR. SLATER:

17 Q. Alternatives to the use of the Prolift®
18 would include Gynemesh® PS, right? You can just cut
19 the mesh and use it as you deem fit in the patient,
20 right?

21 A. Yes.

22 Q. An alternative to the Prolift® could
23 include native tissue repair, right?

24 A. Yes.

1 Q. An alternative to the Prolift® could
2 include other -- rephrase.

3 One of the alternatives to the Prolift®
4 would have been other mesh kits that didn't have arms;
5 that was another option, right?

6 A. Right.

7 Q. One of the alternatives to the Prolift®
8 was to use Ultrapro in the Prolift® which ultimately
9 was marketed as Prolift+M®, correct?

10 A. Right, if that was available at the
11 time.

12 MR. SLATER: Move to strike after
13 "right."

14 BY MR. SLATER:

15 Q. One of the alternatives to the use of
16 Gynemesh® PS would be suture repair, correct?

17 A. It's an alternative, yes.

18 Q. One of the alternatives to Gynemesh® PS
19 would be to take Ultrapro mesh and cut it, flat sheets
20 of Ultrapro, right?

21 A. Yeah, but I don't think that Ultrapro
22 was approved in the vagina as a flat sheet of mesh
23 ever.

24 Q. You could do it off-label?

1 A. You could.

2 Q. Initially, Gynemesh® PS was used -- let
3 me ask the question differently.

4 Initially, before Gynemesh® PS was
5 marketed, doctors would cut Prolene Soft mesh and use
6 it to treat vaginal prolapse, correct, off-label?

7 A. I suppose they did, but I didn't do
8 that.

9 MR. SLATER: Move to strike from "but"
10 forward.

11 BY MR. SLATER:

12 Q. Have you ever written warnings for a
13 medical device?

14 A. No.

15 Q. Have you ever, other than your work as
16 an expert here, studied any sources of standards for
17 warnings for medical device?

18 A. I have looked at some of the standards.

19 Q. As part of your work as an expert?

20 A. As part of my work as an expert.

21 Q. You cited the blue book memo from the
22 FDA and Ethicon standard operating procedure?

23 A. Yes, I've looked at those.

24 Q. That standard operating procedure is

1 your understanding that's the standard that Ethicon now
2 applies?

3 A. Yes.

4 Q. Is it your understanding that's
5 consistent with their prior standards?

6 A. Yes.

7 Q. What's your basis for that
8 understanding?

9 A. I only looked at the standard operating
10 agreement, and I can't tell you about whether it's
11 changed or not over the years.

12 MR. SLATER: I'm going to stop and save
13 my last four minutes for follow-up on Maha's
14 blistering direct, cross, whatever you want to
15 call it.

16 BY MS. KABBASH:

17 Q. Dr. Fleischmann, I'm going to ask you
18 some follow-up questions on the questions that you were
19 asked earlier today.

20 You were asked about whether your
21 opinions are contained in your report.

22 Are your opinions also contained in the
23 testimony that you've provided at your deposition
24 today?

1 MR. SLATER: Objection.

2 THE WITNESS: Yes.

3 BY MS. KABBASH:

4 Q. You were asked some questions earlier
5 today about a modified procedure to the Prolift®
6 anterior that you employed.

7 Do you recall that?

8 A. Yes.

9 Q. Okay. And you testified that at some
10 point in time after you started using Prolift®, you
11 would take the straps of a Prolift® posterior and
12 attach them to the anterior portion.

13 Do you recall that?

14 A. Yes.

15 Q. At some point in time did you start
16 employing the Prolift® total device in a manner
17 consistent with the IFU?

18 MR. SLATER: Objection.

19 THE WITNESS: Yes, I did do that.

20 BY MS. KABBASH:

21 Q. And why did you do that?

22 A. Because I was getting some apical
23 recurrences in uterine prolapse in the modified
24 technique I was using, so I then began to do the total

1 technique and had much better outcomes.

2 Q. And was the total technique that you
3 employed consistent with the IFU as those instructions
4 were set forth by Ethicon?

5 A. Yes.

6 MR. SLATER: Objection.

7 BY MS. KABBASH:

8 Q. Ultimately, did you find that the
9 Prolift® total method -- strike that.

10 Ultimately, did you find that your use
11 of the Prolift® total improved your patients'
12 experiences with their prolapse repair?

13 MR. SLATER: Objection.

14 THE WITNESS: I had less recurrences of
15 the apicals, so, yes, I would say they did.

16 BY MS. KABBASH:

17 Q. And in your use of the Prolift® total,
18 did you implant mesh into the posterior vaginal wall of
19 the vagina?

20 A. I did.

21 Q. If you can pull out the Exhibit 8, which
22 was your letter to Scott Jones, do you have that there
23 among the exhibits?

24 A. Yes, I have it.

1 Q. Mr. Slater asked you about some language
2 at the end of this letter where you indicated -- and
3 this letter is dated November 2009; is that correct?

4 A. Yes.

5 Q. And you went on to use Prolift® for --
6 and Prolift+M®, I should say, for three years after
7 when this letter was written; is that right?

8 A. Correct.

9 Q. And the last two lines of this letter
10 say, "Remember not many pelvic surgeons like putting
11 mesh over the rectum when the main problem is
12 cystocele. It just doesn't make sense."

13 Do you see you wrote that at that time?

14 A. Yes.

15 Q. Did you later come to find that it did
16 make sense to, in appropriate patients, implant mesh on
17 the posterior vaginal wall?

18 MR. SLATER: Objection.

19 THE WITNESS: Yes, I found that it was
20 more beneficial in cases even when there was
21 cystocele and mild uterine prolapse to support
22 the uterus with a posterior side.

23 BY MS. KABBASH:

24 Q. And why was that? Why did you find that

1 that was useful?

2 A. Because I just wasn't getting -- I
3 was -- one of the main differences between doing the
4 Prolift® and what I was doing before when I was cutting
5 my own PS, I was doing hysterectomies on everybody.
6 With Prolift® I was really trying to do uterine sparing
7 surgery, which I thought benefited women.

8 Now by leaving the uterus it needed
9 better support than just the anterior portion would
10 give us, so by supporting the back wall of the uterus,
11 I was getting better uterine support, and you have to
12 remember, I'm operating on patients who all have very
13 severe prolapse, either stage 3 or stage 4. So almost
14 everybody has a little element of uterine prolapse if
15 they have a uterus.

16 Q. And after -- I think I just asked you,
17 after you wrote this letter, you continued to use
18 Prolift+M®; is that right?

19 A. I did.

20 Q. Did you use the Prolift+M® until that
21 product was discontinued?

22 A. I did up until the day.

23 Q. Okay. Did you see a difference in your
24 patient outcomes between the -- your use of the regular

1 Prolift® device and the Prolift+M® in your patients?

2 A. I didn't have a difference in my --
3 well, with the exception that I was then doing the
4 total Prolift®, I would say that my outcomes were
5 better, but I didn't attribute that to the mesh, I
6 attributed it to the fact I was putting mesh on the
7 back side, which I could have done with Prolift® too, I
8 just never really got there with that device. So I did
9 see better outcomes from that point.

10 The only outcome that I felt was a
11 little bit better is that there was less palpation or I
12 would call it a mesh appreciation behind the vaginal
13 wall with M, but in terms of patient's happiness, with
14 the exception I had better outcomes with recurrences,
15 no, it was the same.

16 Q. Did you see any difference in patient
17 outcomes with respect to complications, complication
18 rates between the Prolift+M® mesh and the Prolift®
19 mesh?

20 A. No, but my exposure rate was lower, but
21 I also attributed it to the fact by the time 2011, 2012
22 came around, I was getting very good at that repair.
23 So I really was shocked when someone came in with an
24 exposure, unlike in previous years, where I sort of

1 expected a certain amount of my patients to have an
2 exposure. At that point exposures were always a little
3 bit shocking.

4 Q. You were asked questions earlier today
5 by Mr. Slater about whether you had seen a
6 PowerPoint -- or strike that -- whether you had seen a
7 presentation of data from TVM surgeons where a 19.6%
8 symptomatic contraction rate was reported.

9 Do you recall being asked about that?

10 A. Yes.

11 Q. In your report, in your preparation of
12 your report, have you relied on large meta-analyses
13 that have studied the use of transvaginal mesh to treat
14 prolapse?

15 MR. SLATER: Objection.

16 THE WITNESS: I have. I looked at many
17 of those meta-analyses.

18 BY MS. KABBASH:

19 Q. Have you also reviewed and relied on
20 several randomized, controlled trials that specifically
21 analyzed Prolift®?

22 A. Yes.

23 Q. And in those studies did you see any
24 evidence or anything similar to a 19.6% rate of

1 symptomatic contraction?

2 A. No, because that would imply to me like
3 that level of dyspareunia or something like that,
4 symptomatic contraction, and I did not see that.

5 Q. You were asked earlier today if you were
6 a materials expert.

7 Do you recall that?

8 A. Yes.

9 Q. If you could turn to your opinions at
10 the end of your report, Page 65 specifically, do you
11 have that in front of you?

12 A. Yes.

13 Q. If you look at Opinion Number 3, I'll
14 read that into the record, it says, "The Gynemesh® PS
15 used in Prolift® and the Ultrapro mesh used in
16 Prolift+M® are appropriate, effective and safe
17 materials for use in this indication. Polypropylene
18 mesh and sutures have been used as implant for decades.
19 Based on my review of the peer-reviewed medical
20 literature and my surgical experience implanting these
21 devices and treating patients who have had them
22 implanted, the pore sizes of these meshes are
23 appropriate."

24 Do you see that?

1 A. Yes.

2 Q. With respect to the first sentence that
3 these meshes are appropriate, effective and safe
4 materials for use in this indication, do you continue
5 to hold that opinion?

6 MR. SLATER: Objection.

7 THE WITNESS: I hold the opinion that I
8 am a materials expert when it comes to these
9 particular materials, because I've used them
10 for so long and in so many patients, but I
11 wouldn't say that I am a broad spectrum
12 materials expert, or that is my career.

13 BY MS. KABBASH:

14 Q. And your opinion that you just stated,
15 is that also based on your review of the medical
16 literature that is set forth in this report and on your
17 reliance list?

18 MR. SLATER: Objection.

19 THE WITNESS: Exactly.

20 BY MS. KABBASH:

21 Q. You were asked lots of questions today
22 about the specific findings of various clinical
23 studies.

24 Do you recall that?

1 A. Yes.

2 Q. Have any copies of any clinical studies
3 been put before you today?

4 A. No, they haven't.

5 Q. Would it have been helpful to you to
6 have those articles in front of you so that you could
7 actually confirm the findings of those studies as they
8 were represented to you?

9 MR. SLATER: Objection.

10 THE WITNESS: Yes, it would have been
11 helpful.

12 BY MS. KABBASH:

13 Q. You were asked questions earlier today
14 about whether you had participated in the drafting of
15 warnings for medical devices.

16 Do you recall that?

17 A. Yes.

18 Q. On Page 66 of your report, I'll read
19 into the record the first part of Opinion Number 8, it
20 says, "The Instructions for Use, professional education
21 materials, and patient brochures accurately reflect the
22 risks of these products as they are reported in the
23 medical literature and are consistent with my training
24 and extensive surgical experience."

1 Do you see that?

2 A. Yes.

3 Q. Does that continue to be your opinion?

4 A. My opinion is for the purpose of these
5 products that I do have -- I am an expert in the area
6 of being able to define whether these risks -- the
7 risks associated with the device were accurately
8 reflected.

9 Q. And is that -- are those opinions based
10 on your review of the medical literature?

11 A. Yes, they are.

12 MR. SLATER: Objection.

13 BY MS. KABBASH:

14 Q. As a matter of fact, if you look on Page
15 61 to 62 of your report, there are five numbered
16 paragraphs there.

17 Do you see that?

18 A. Yes.

19 Q. In those five numbered paragraphs, do
20 you set forth precisely what the basis of your opinions
21 are with respect to the warnings for Prolift®,
22 Prolift+M® and Gynemesh® PS?

23 MR. SLATER: Objection.

24 THE WITNESS: Yes, I do.

1 BY MS. KABBASH:

2 Q. And has there been any discussion today
3 at this deposition which changes that body of
4 information as you've set it forth on those two pages
5 of your report?

6 MR. SLATER: Objection.

7 THE WITNESS: No, there's been nothing
8 that's been discussed that would change that.

9 BY MS. KABBASH:

10 Q. You were asked earlier today about
11 whether it's possible that women who have had a
12 Prolift® or Prolift+M® mesh would have to go to the
13 operating room for revision of mesh exposure more than
14 once.

15 Do you recall that?

16 A. Yes.

17 Q. In your review of the meta-analyses that
18 have looked at the transvaginal use of mesh to treat
19 prolapse and the RCT specifically regarding Prolift®,
20 have those items of literature reflected a large
21 proportion of women who have had to go back for more
22 than one revision surgery to treat a mesh exposure?

23 MR. SLATER: Objection.

24 THE WITNESS: No, they don't.

1 BY MS. KABBASH:

2 Q. And on Page 66 of your report, Opinion
3 Number 7 is "Contraction is described in the literature
4 but cannot be differentiated from the concept of
5 over-tensioning which is clearly warned about in the
6 product IFUs and the Prolift® Surgeon's Resource
7 Monograph which specifically state that the mesh should
8 lay in loosely."

9 Do you see that?

10 A. Yes.

11 Q. Does that remain your opinion to this
12 day?

13 MR. SLATER: Objection.

14 THE WITNESS: Yes.

15 BY MS. KABBASH:

16 Q. Do you hold that opinion to a reasonable
17 degree of medical certainty?

18 A. Yes, I do.

19 Q. Have any of the discussions that we have
20 had today altered your opinion on that point?

21 A. No.

22 MS. KABBASH: That's it.

23 MR. SLATER: I have five follow-up
24 questions.

1 BY MR. SLATER:

2 Q. First of all, you were asked about
3 whether it would have been helpful to have various
4 articles or studies in front of you. You could have
5 brought them and had them here to review.

6 You didn't bring them, correct?

7 MS. KABBASH: Objection.

8 THE WITNESS: I don't have the articles
9 with me, no.

10 BY MR. SLATER:

11 Q. You could have brought them, right?

12 MS. KABBASH: Objection.

13 THE WITNESS: I could have.

14 BY MR. SLATER:

15 Q. The meta-analyses on mesh, they're not
16 all Prolift®, correct? It's about all different types
17 of mesh products and mesh devices, right?

18 A. Transvaginal mesh in general.

19 Q. The RCTs on Prolift® you just referred
20 to with defense counsel, are any of those RCTs where
21 they specifically had an endpoint to evaluate for
22 retraction of the mesh or painful retraction of the
23 mesh, where that was actually an endpoint they were
24 studying?

1 MS. KABBASH: Objection.

2 THE WITNESS: Dyspareunia only, not
3 retraction or contraction, as you call it.

4 MR. SLATER: Move to strike.

5 BY MR. SLATER:

6 Q. That answer is no, correct?

7 MS. KABBASH: Objection.

8 THE WITNESS: Not retraction or
9 contraction specifically.

10 BY MR. SLATER:

11 Q. The studies that you said don't show a
12 large number of women with multiple erosions and
13 multiple surgeries, you were just asked about that,
14 most of those studies are not long-term studies, right?

15 A. The longest term we have is five years
16 to seven years.

17 Q. You were asked about whether anything
18 today changed your opinions in any way.

19 Is there anything I can tell you that
20 would actually get you to say, you know what, now that
21 you've shown me this, I will say that the benefits are
22 outweighed by the risks of the Prolift®? Is there
23 anything I could show you, something from an internal
24 document or any information I could show you that you

1 would say, okay, it's an unreasonable risk-benefit
2 profile?

3 A. From an internal document?

4 Q. From any source.

5 MS. KABBASH: Objection, calls for
6 speculation.

7 MR. SLATER: I'm giving you example,
8 internal documents, internal information,
9 anything.

10 THE WITNESS: Not from an --

11 MS. KABBASH: Objection.

12 THE WITNESS: -- internal document
13 because I have all the information I need right
14 now, especially doing the product, you know.

15 BY MR. SLATER:

16 Q. Is there anything I could show you or
17 tell you that would cause you to sit back and say, you
18 know what, based on that, the risk-benefit profile is
19 not reasonable for the Prolift®?

20 MS. KABBASH: Objection, calls for
21 speculation.

22 BY MR. SLATER:

23 Q. Is there anything I could show you that
24 would convince you of that?

1 A. I can't think of anything you would show
2 me that would convince me of that.

3 MR. SLATER: No other questions.

4 BY MS. KABBASH:

5 Q. Dr. Fleischmann, with respect to the
6 Prolift® RCTs that you have reviewed and the
7 meta-analyses, Mr. Slater asked you if they had as an
8 endpoint contraction.

9 Based on your review of those articles
10 and how those studies were set up and the complications
11 that they tracked, do you have any reason to believe
12 that a finding of a clinical symptom of contraction
13 would have been excluded from the study?

14 MR. SLATER: Objection, multiple
15 grounds.

16 THE WITNESS: Not excluded, I just don't
17 know it had a clinical manifestation for them
18 to be able to include it in a complication part
19 of the study.

20 BY MS. KABBASH:

21 Q. And you didn't note any findings in the
22 study that would have demonstrated those clinical
23 manifestations, correct?

24 MR. SLATER: Objection.

1 THE WITNESS: Exactly.

2 MS. KABBASH: That's it.

3 (Witness excused.)

4 (Deposition concluded at 4:14 p.m.)

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C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR

CSR #XI01497 Notary Public

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4 PAGE LINE CHANGE

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1 ACKNOWLEDGMENT OF DEPONENT

2
3 I, NICOLE B. FLEISCHMANN, M.D., do
4 hereby certify that I have read the foregoing
5 pages, and that the same is a correct
6 transcription of the answers given by me to the
7 questions therein propounded, except for the
8 corrections or changes in form or substance, if
9 any, noted in the attached Errata Sheet.

10
11
12
13 _____
14 NICOLE B. FLEISCHMANN, M.D. DATE

15 Subscribed and sworn to before me this

16 _____ day of _____, 2017.

17 My commission expires: _____

18 _____
19 Notary Public
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